Decision Summary

The Centers for Medicare and Medicaid Services (CMS) has concluded that the evidence does not demonstrate that thermal intradiscal procedures improve health outcomes. Thus, CMS has determined that TIPS are not reasonable and necessary for the treatment of low back pain. Therefore, CMS is issuing a national noncoverage determination for TIPs under §1862(a)(1)(A) of the Social Security Act.

Back to Top

Decision Memo

TO: Administrative File: (CAG-#00387N)
Thermal Intradiscal Procedures

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SUBJECT: Coverage Decision Memorandum for Thermal Intradiscal Procedures (TIPs)

DATE: September 29, 2008

I. Decision

The Centers for Medicare and Medicaid Services (CMS) has concluded that the evidence does not demonstrate that thermal intradiscal procedures improve health outcomes. Thus, CMS has determined that TIPS are not reasonable and necessary for the treatment of low back pain. Therefore, CMS is issuing a national noncoverage determination for TIPs under §1862(a)(1)(A) of the Social Security Act.

II. Background

Chronic pain is the most universal form of human stress and millions of Americans suffer from pain-related problems (Salovey, Seiber et al. 1992). Low back pain is a common condition with sixty to eighty percent of U.S. adults afflicted at some time during their life (U.S. Preventive Services Task Force 1996).

Low back pain can be defined as symptoms of pain, muscle tension, or stiffness localized below the costal margin and above the inferior gluteal folds, with or without leg pain (Manek, MacGregor 2005). Low back pain can be thought of as being either nonspecific or specific. In specific types of low back pain, the symptoms are caused by pathological conditions such as spinal fractures, cancer, or infection and can be identified and treated appropriately (Manek, MacGregor 2005). Approximately 90% of low back pain is of the nonspecific type (Manek, MacGregor 2005) which means that the cause of this pain is difficult to identify. In nonspecific low back pain, most patients' symptoms resolve satisfactorily within a relatively short time span. In the 5 – 10% of patients whose pain does not satisfactorily resolve, the symptoms can be disabling. Some psychosocial risk factors for the progression to chronicity have been identified (Manek, MacGregor 2005). Weiner reported documentation of nonspecific low back pain in Medicare beneficiaries growing in epidemic proportions. It is unclear if this is a true increase in low back pain prevalence (Weiner, Kim et al. 2006).

In general, the social and economic impact of chronic pain is enormous (Salovey, Seiber et al. 1992). However, in 2008, Martin reported, "Despite rapidly increasing medical expenditures from 1997 to 2005, there was no improvement over this period in self-assessed health status, functional disability, work limitations, or social functioning among respondents with spine problems" (Martin, Deyo et al. 2008). The growing list of treatment approaches offered as solutions for chronic low back pain (CLBP) has created confusion and frustration for the patients as well as clinicians and the third party payors responsible for providing access to care (Haldeman, Dagenais 2008a).

Identifying the cause for nonspecific low back symptoms remains challenging. Haldeman stated, "…we do not know the origin of low back pain in the majority of cases…" and attributes this conundrum to the unique anatomic complexity of the spine (Haldeman 1999). Weiner reported causative underlying pathology difficult to determine because low back pain, a complex clinical syndrome, derives from a multitude of causes, such as mechanical and nonmechanical factors and visceral disease (Weiner, Kim et al. 2006). Neurophysiologic mechanisms of pain sensation are poorly understood, adding to the difficulty in localizing the pain source (Haldeman 1999). Nachemson related the complexity of back pain not only to local pathology but also to biochemistry, pain physiology, brain science, psychology, sociology and economics (Schoene 2006).

Frequently, persistent low back pain is attributed to a damaged intervertebral disc, which bears some of the highest loads in the human body and is almost avascular (Huang, Sandhu 2004). Disc damage, or degeneration, can occur as an ongoing process where ultimately the disc's reparative capacity is overwhelmed, leading to continued changes. Huang and Sandhu stated, "it is not surprising that DDD [degenerative disc disease] is a common phenomenon in middle age and a universal condition in old age." While from a simple mechanical aspect it could be hypothesized that DDD is a cause for pain, disc degeneration is also observed in individuals without pain (Boden, Davis et al. 1990). While many have focused on the disc as the cause of pain, Nachemson felt its role in back pain causation was no more proven than those of other structures (Schoene 2006).

CLBP is a condition that is treated across many medical/surgical specialties. The education, training skills and experience of this diverse group have an influence on the individual practitioner's viewpoint on the management of CLBP (Haldeman, Dagenais 2008b). The development of reliable, high quality evidence to support the different treatment modalities faces its own set of challenges. The explosion of orthopedic technology has exponentially increased the understanding of the mechanics, biology and natural history of the spine (Shah, Albert et al. 2005). However, validation of new technologies is crucial to establish both safety and efficacy (Shah, Albert et al. 2005). Weinstein counseled, "Despite the meaning of the phrase, 'technological advances' are not always improvements. …It is true that new treatments can allow for improved care, but we should not assume they automatically do" (Weinstein 2007).

In 2004, Deyo offered, "The history of treatments for back and neck pain is generally one of small increments in benefit." He went on to say that it is hard to prove that most treatments provide greater improvements than the nonspecific effects of natural history, placebo and regression to the mean for both acute and chronic pain. Deyo further stated, "The literature is replete with conflicting results, modest effects, and weak studies." Deyo noted the scarcity of large trials in musculoskeletal diseases that are commonplace in cardiovascular disease and oncology (Deyo 2004). Haldeman stated, "…the question that needs to be answered is whether any treatment should be offered and widely used before there being sufficient research evidence to establish its efficacy, safety, and cost effectiveness" (Haldeman, Dagenais 2008b). In relation to treatment options for CLBP, Haldeman's assessment was, "...we are still in the era of caveat emptor (buyer beware)" (Haldeman, Dagenais 2008b). New technologies continue to be brought into practice with poorly designed studies that provide a false sense of security to practicing physicians about patient outcomes (Weinstein 2007).

Although discography is thought by some to be important in diagnosing discogenic back pain, "…controversy remains as to the accuracy and specificity of discography because of the inability to understand the mechanism which produces pain" (Peng, Wu et al. 2005). Provocative discography, described in the 1940's as a method of imaging discs by injecting contrast into the nucleus pulposus, has been controversial from its earliest use (Carragee 2000). In 2002, Jarvik and Deyo characterized the diagnosis of internal disc disruption (IDD) by provocative discography as controversial. In addition, the clinical importance of identifying high-intensity zones (HIZ), describing the presence of focal high signal in the posterior annulus fibrosus seen on imaging, which presumably represent annular tears, remains controversial (Jarvik, Deyo 2002). It seems the clinical importance of HIZ has not gained general acceptance in the spine care community at this time.

The initial treatment of pain believed to be caused from degenerative disc disease is conservative care. Conservative care can include physical therapy, manipulation, massage, pain medications, and exercise. The majority of patients will have acceptable results with a non-surgical approach. When patients fail conservative care, surgery becomes an option. Until recently in the United States, surgical options available for degenerative disc disease have ranged from discectomies (open or microsurgical) to percutaneous nucleotomies, chemical and thermal nucleolysis and/or spinal fusion (Gibson, Wassell 2005). The last two decades have provided rapid technological advancements which have made minimal access spine surgery possible (Thongtrangan, Le et al. 2004).

Enhancement of patient outcomes by facilitating a quicker return to daily activities, diminishing pain and complications, and decreasing overall healthcare costs has motivated changes in spine surgeries over the years (Samartzis, Shen et al. 2007). Minimal access or minimally invasive spine surgery began to develop with the improvements in instrumentation and imaging (Samartzis, Shen et al. 2007). Derby stated, "The rationale for heating intervertebral discs was strongly influenced by animal and clinical investigations testing the ability of heat to stabilize joints by modifying collagen" (Derby, Baker et al. 2008).

The evolution of thermal intradiscal procedures involved the use of electrical and radiofrequency energy to apply or create heat within the disc to treat discogenic pain. Percutaneous thermocoagulation intradiscal techniques involve the insertion and heating of a catheter/probe(s) in the disc under fluoroscopic guidance (Urrutia, Kovacs et al. 2007). Derby stated, "The goals of thermal disc treatments are to remove unwanted tissue such as herniated discs, create a seal to limit expression of matrix components, shrink collagen tissue, and destroy nociceptors[1]. Although intradiscal heating can be accomplished through a variety of means, including electrocautery, thermal cautery, laser, and radiofrequency energy (RFE); most current intradiscal thermal treatments are performed using RFE" (Derby, Baker et al. 2008).

A review of the current literature reveals that the mechanism of the disorder, nonspecific CLBP, as well as the mechanism of action of the thermal intradiscal procedures remain uncertain. Derby reported that despite numerous in vivo and in vitro studies using human and animal models, the precise relieving mechanism of intradiscal heating is unclear. He went on to state that the theoretical explanations of mechanism of action are changes in disc biomechanics, annular contraction, thermally induced healing response, sealing of annular tears, annular denervation and/or decreased intradiscal pressure (Derby, Baker et al. 2008). Finch stated that attempts at applying the principals of pain reduction through thermal destruction of afferent nociceptive fibers to the lumbar intervertebral disc have not proven easy, due to the complexity of the afferent nociceptive pathways which, to date, are only partially understood (Finch 2004).

Derby summarized, "RFE may be applied with unipolar or bipolar probes. Similar to electrocautery, with unipolar RFE, currents pass through the probe to the body and to a grounding pad. The bipolar probe allows energy to pass through positive and negative poles on the probe, theoretically decreasing collateral damage. The bipolar devices may allow for greater control and focus of heat energy. A modification of the bipolar probe has been termed "coblation," which has been claimed to generate plasma of high-energy inonized particles in the tissues surrounding the probe rather than a traditional heat lesion. The plasma can disrupt organic bonds, thus allowing debridement and effective heat treatment of soft tissues" (Derby, Baker et al. 2008). TIPs are proposed as an alternative to spinal fusion.

Direct radiofrequency (RF) lesioning of a disc was first performed in 1988 by Sluijter. This involved inserting a RF electrode into the central disc nucleus similar to provocative discography. With the tip of the electrode reaching temperatures of 70° C for several minutes, a lesion was created (Finch 2004). Subsequently, multiple lesions were created in the vicinity of the posterolateral annulus. A flexible RF catheter was subsequently introduced. This catheter is steered into position in the outer annulus from the contralateral side to the annular tear. The subsequent application of RF energy raises the temperature to 65° C in incremental steps over ten minutes. The spread of thermal energy was measured by placement of a thermocouple placed adjacent to the annular tear (Finch 2004).

The scope of this national coverage analysis (NCA) is TIPs which involve percutaneous intradiscal techniques utilizing devices that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for coagulation and/or decompression of disc material to treat symptomatic patients with annular disruption of contained herniated disc, to seal annular tears or fissures, or destroy nociceptors for the purpose of relieving pain. This includes techniques that use single or multiple probes/catheters, which utilize a resistance coil or other delivery system technology, are flexible or rigid, and are placed within the nucleus, the nuclear-annular junction or the annulus. TIPs are commonly identified as intradiscal electrothermal therapy (IDET), intradiscal thermal annuloplasty (IDTA), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), radiofrequency annuloplasty (RA), intradiscal biacuplasty (IDB), percutaneous (or plasma) disc decompression (PDD) or coblation, or targeted disc decompression (TDD). At times, TIPs are identified or labeled based on the name of the catheter/probe(s) that is used (e.g. SpineCath, discTRODE, SpineWand, Accutherm, or TransDiscal electrodes). Each technique or device has its own protocol for application of the therapy. Percutaneous disc decompression or nucleoplasty procedures that do not utilize a radiofrequency energy source or electrothermal energy (such as the disc decompressor procedure or laser procedure) are not within the scope of this NCA.

In December of 2006, CMS received a letter from the North American Spine Society (NASS) providing comment on the notice of the Final Rule for 2007 Medicare Physician Payment Schedule which addressed IDET (published in December 2006 Federal Register). NASS stated, "It is our belief that IDET is the subject of significant controversy among experts and that the scientific evidence demonstrating efficacy for IDET is inconsistent. At best, there is a small subset of younger, highly selected patients who obtain temporary benefit. At worst the procedure is no better than placebo. In addition, there have not been studies done demonstrating efficacy in patients over the age of 60." The Society concluded, "At this time, the available scientific literature evaluating the clinical efficacy of IDET is conflicting. NASS does not believe this procedure has been well studied or its efficacy established in the Medicare population. If performed, NASS strongly recommends strict adherence to the selection criteria utilized in the Pauza study. Even in the best clinical practice, when these criteria are rigidly applied, only a relatively small number of patients obtain near complete relief. Because many people experience low back pain, the procedure could become quite costly without a demonstrated improvement in health benefit if it is applied indiscriminately and for improper indications."

In that letter and in subsequent communications, NASS suggested that CMS review the literature on IDET to determine if IDET should be reimbursed. After a preliminary review of the literature, CMS identified numerous techniques operating on essentially the same premise and for essentially the same indications and decided to open a national coverage analysis on TIPs. CMS recognizes that there are some differences among the techniques and devices employed in TIPs; however, we believe the various techniques utilized for TIPs use the same function and seek the same desired outcome (the application or creation of heat and /or disruption within the disc to relieve pain) and should be grouped under one NCA.

III. History of Medicare Coverage

Medicare does not currently have a national coverage determination (NCD) on TIPs. Decisions on coverage for TIPs have been made by the local contractors. A search of the local coverage decisions (LCDs) database for thermal intradiscal and intradiscal electrothermal therapy identified thirteen LCDs from the local Medicare contractors. Nine policies stated non coverage for Nucleoplasty and IDET (annuloplasty) or other similar minimally-invasive ablative procedures – using radiofrequency, laser or direct heat energy source - and their associated services because these services are not proven to be effective and are considered to be not reasonable and necessary. Four LCDs stated that regardless of the technique, coagulation and decompression of disc material by electrothermal or radiofrequency techniques were considered investigational. However, these four LCDs allowed individual consideration for IDET for patients meeting strictly defined criteria.

Benefit Category

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. §1812 (Scope of Part A); §1832 (Scope of Part B); §1861 (Definitions of Services, Institutions, Etc.). TIPs would be eligible for coverage under Part B, as physician services, under §1861(q), hospital services incident to physicians' services rendered to outpatients under 1861(s)(2)(B) and ambulatory surgical centers under 1832(a)(2)(F)(i). This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

IV. Timeline of Recent Activities

January 15, 2008	CMS initiates opening a NCD for TIPs. Initial 30-day public comment period begins.
February 13, 2008	Meeting with Smith & Nephew and other interested parties on IDET.
February 14, 2008	Initial 30-day public comment period closes.
April 3, 2008	Meeting with Baylis Medical on Biacuplasty.
July 15, 2008	Proposed Decision Memorandum posted and 30 day public comment period begins.
August 4, 2008	Meeting with Smith & Nephew and other interested parties on IDET.
August 14, 2008	Meeting with Society representatives.

September 3, 2008	Telephone conference with interested parties and Smith & Nephew on IDET.
September 4, 2008	Meeting with Baylis Medical on Biacuplasty.

V. Food and Drug Administration (FDA) Status

There are numerous catheters that have received 510(K) clearance from the FDA for use in thermal procedures. Some catheters have a specific indication for use in the intervertebral disc and many are indicated for the creation of heat lesions for the relief of pain. Some of the catheters identified for use in the intervertebral disc are identified below. This is not intended to be a complete list of all the catheters that may be used in thermal intradiscal procedures. A point of interest is that all the catheters listed below received 510(K) clearance because they were determined to be substantially equivalent to a predicate device and those predicate devices were determined to be substantially equivalent to another predicate device and so on. It should be noted that TIPs are the topic of this NCA; not specific catheters used in the application of heat within the intervertebral disc.

The IDET technique is commonly identified with the use of the SpineCath Intradiscal catheter. Original 510(K) clearance was obtained by Oratec. In 2002 Oratec was acquired by Smith & Nephew. In 1998 Oratec obtained 510(K) clearance from the FDA for the SpineCATH Intradiscal Catheter (K974464) (substantially equivalent to Oratec EndoTAC Monopolar Cautery Probe K972358). The identified indication for use was for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated disc. The catheter was for use only with the Oratec generator. (Link to FDA web page:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&id=K974464)

Subsequently, in 1999 Oratec obtained 510(K) clearance from the FDA for the SpineCATH intradiscal catheter Model 9200 (K993967) (predicate device – SpineCATH Intradiscal Catheter K974464). The intended use was for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. The catheter was intended for use with Oratec ElectroThermal Spine System Generator. (Link to FDA web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&id=K993967)

In October of 2000, Radionics obtained 510(K) clearance for the Radionics RF Disc Catheter Electrode System (K001741) (predicate devices - Oratec SpineCATH Intradiscal Catheter K974464 and Radionics RFG-3CPlus RF Lesion Generator K982489). This catheter seems to be associated with the PIRFT technique. The indication for use of this system, in combination with the Radionics RFG-3CPlus RF lesion generator, was for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs. (Link to FDA web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/PMNSimpleSearch.cfm?db=PMN&ID=K001741)

In January of 2002, Oratec Interventions, Inc., received 510(K) clearance from FDA for the Nucleotomy Intradiscal Catheter (K013622) (predicate device - SpineCATH Intradiscal Catheter K993967). The intended use was for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. (Link to FDA web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=6341)

In September of 2003, Baylis Medical Transdiscal system received 510(K) clearance from the FDA (K031951) (predicate device not identified on FDA website). The intended use was for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. (Link to the FDA web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=12189)

In January of 2007, the Baylis Medical TransDiscal system received 510(K) clearance from the FDA (K062937) (predicate devices – Baylis TransDiscal System K031951 and the Baylis Pain Management Cooled Probe K053082). (This catheter seems to be associated with the Biacuplasty technique.) The intended use was the creation of RF lesions in nervous tissue including that which is situated in intervertebral disc material. The two TransDiscal probes and the Pain Management Pump unit, connected to the Baylis Pain Management Generator, deliver the RF energy. (Link to FDA web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=22934)

In February of 2008, Smith & Nephew, Inc., received 510(K) clearance from the FDA for the Smith & Nephew Intradiscal Catheter System (K073466) (predicate devices – Nucleotomy Catheter K013622 and the Spinecath Intradiscal Catheter K993967). This system consisted of the Spinecath Intradiscal Catheter and the Acutherm Decompression Catheter and was used as part of the IDET and TDD techniques. The intended use of the Spinecath Intradiscal Catheter is identified above. The intended use of the Acutherm Decompression Catheter was for the coagulation and decompression of disc material to treat symptomatic patients with contained herniated discs. (Link to FDA web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=26487)

VI. General Methodological Principles

When making national coverage determinations under §1862(a)(1)(A) of the Social Security Act, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix A. In general, features of clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

Public comment sometimes cites the published clinical evidence and gives CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

Assessment of outcome in the treatment of chronic low back pain

The evidence CMS examined had as its focus health outcomes, meaning the benefits and harms of a particular treatment. Outcomes that are usually heavily weighted by CMS - morbidity and mortality - are difficult to examine in the context of treatment for CLBP because pain is a symptom, not a disease. Sustained improvement in pain perception and a reduction in the pain-related functional restriction are generally the focus of study outcomes as opposed to managing a disease such as diabetes where measures such as progression to renal failure, blindness, and death are used. Measuring a reliable improvement in chronic pain attributable to a treatment is problematic as pain is particularly responsive to the placebo effect. Additionally, measuring the course of back pain is difficult as the natural history of this symptom is understood to be extremely variable (von Korff 1994). Therefore, clinical trials with appropriate controls utilizing independently assessed validated instruments are most heavily weighted. The measurement of treatment effect for low back pain has shifted from physician-based assessment (with outcomes of excellent, good, fair, and poor) to a patient-based self-report of pain and disability (Hagg, Fritzell et al. 2003).

Measurement of the effects of treatment for chronic low back pain should reflect the complex, multifaceted nature of the disorder (Bombardier 2000; Deyo, Battie et al. 1998). Groups have advocated for inclusion of standardized measures in five areas including function, symptoms, general health status, work disability, and satisfaction with care (Deyo, Battie et al. 1998; Bombadier 2000b). Standardizing the measures facilitates study comparison. The most commonly used measures of back specific function include the Roland-Morris Disability Questionnaire (RDQ) and the Oswestry Disability Index (ODI). The Low Back Outcome Score (LBOS) is a lesser used measure. These measures are an indication of the extent to which a person’s functional level is restricted by pain. General health status can be measured with the SF-36, which has the advantage of norm-based scoring on diverse populations and has been validated for back pain (Bombadier 2000b). Pain intensity can be measured with the bodily pain subscale of the SF-36 (Bombadier 2000b) or the visual analog pain scale (VAS) (Deyo, Battie et al. 1998). While patient satisfaction is important, its measurement is more ambiguous. No single measure is preferred, however various approaches have been suggested (Bombadier 2000b). CMS weights those studies with reliable, validated outcomes most heavily.

With the use of any of these instruments for measurement, a consideration must be given to the clinical meaning of a change in the score (or, for a change in instrument score to be clinically meaningful the patient should experience a change in how he feels or functions). Other considerations include the error of measurement of the instrument used and the clinical importance of a statistically significant score change. In a 2003 study by Hagg of 289 patients treated surgically or non-surgically in a randomized controlled trial, the standard error of measurement of the ODI was four units, with a 95% tolerance interval of 10, and the minimum difference that appeared clinically important was 10 units (Hagg, Fritzell et al. 2003). The minimal clinically important difference of VAS back pain was 18-19 units [on a 100 point scale] with a 95% tolerance interval of 15 (Hagg, Fritzell et al. 2003). These recommendations are similar to those by Ostelo who also noted that when baseline was taken into account a 30% improvement, when comparing before and after measures for individual patients, should be the guide for the minimal important change (MIC) (Ostelo, Deyo et al. 2008). Ostelo, in an aim towards international consensus regarding minimal important change, noted that workshop participants (during the Low Back Pain Forum VIII) stressed that proposed MIC values were for individual rather than group changes (Ostelo, Deyo et al. 2008). The clinically important change is based on an individual, but is often misused to compare the difference in mean scores between two groups, but this is not a clinically important difference (MedCAC 2006).

The SF-36 Health Survey can be used to measure general well-being. Since the SF-36 is not specific to any disease, the disease burden of specific conditions can be compared (Ware 2003b). Of the eight health profiles (36 questions total) that are included in this survey, each can be reported independently, such as bodily pain, or as a composite of subscales such as the mental health component. Norm based data for large diverse populations are available for comparison. For instance, for the general U.S. population the bodily pain mean score is 75.5 (+/-23.6).

In some studies of low back pain treatments, physiologic measures such as segmental mobility (as measured by range of motion) were reported; however, the correlation with clinical outcomes remains unclear. For TIPs, no physiologic outcomes have been reported.

Well-designed clinical trials can provide the strongest evidence for treatment effect. Well constructed randomization protects against bias and inclusion of an appropriate comparator facilitates study interpretation. In pain treatment trials, the natural history of the disease, regression toward the mean and the placebo response are important considerations. For these reasons, an appropriate comparator is necessary for accurate interpretation. Accurate interpretation of pain treatment trials also necessitates reporting of concomitant pain treatments, most importantly analgesic use. In the case of research in the area of pain treatment, more weight will normally be accorded to studies that are designed to guard against the placebo response and where the natural history of the disease and regression toward the mean are accounted for.

Adverse events are important medical outcomes. Patients need this information to make well-informed choices. For instance, for TIPs (including discography), studies that report all infectious, neural, allergic hypersensitivity and vascular complications as well as probe fractures and muscular spasm are desirable. Studies that provide an inclusive examination and explanation of adverse medical events are generally given more weight.

B. Discussion of evidence

1**. Question:**

The development of an assessment in support of Medicare coverage decisions is based on the same general question for almost all requests: "Is the evidence sufficient to conclude that the application of the item or service under study will improve health outcomes for Medicare patients?" For this NCD, the question of interest is:

Is the evidence sufficient to conclude that TIPs will improve health outcomes in the Medicare population with low back pain?

2. External technology assessment (TA)

CMS did not commission an external TA for this NCA; however, a number of external technology assessments were identified in the literature.

California Technology Assessment Forum (CTAF)
October 2003

CTAF conducted a technology review in 2003 of intradiscal electrothermal therapy. The recommendations were that intradiscal thermal therapy with the Radionics RF system and with the Oratec IDET system did not meet CTAF TA criteria.*

* These criteria were not met:
The improvement must be attainable outside the investigational setting.
The technology must be as beneficial as any established alternatives.
The technology must improve the net health outcomes.

National Institute for Clinical Excellence (NICE)
August 2004 and May 2006

In guidance documents, NICE concluded that the evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy (2004), percutaneous disc decompression using coblation (2006), and radiofrequency thermocoagulation (2004) for lower back pain was not adequate to support the use of this procedure without special arrangements for consent and for audit or research.

Institute for Clinical Systems Improvement (ICSI)
April 2002

The ICSI technology assessment committee found:
1. There was no convincing evidence that shows the short or long-term clinical efficacy of this procedure.
2. Short term studies have indicated few adverse effects of IDET, but information on long-term effects was limited.
3. The long-term effects of thermal coagulation of the disk were unknown at that time.

Danish Centre for Evaluation and Health Technology Assessment
December 2003

The Danish centre for evaluation and health technology assessment came to this conclusion on the clinical effect of intradiscal electrothermal therapy for low back pain: "As there was no convincing documentation for the indications and treatment results, in the event that IDET is introduced in Denmark this should take place via a randomized controlled clinical trial."

Cochrane Review
Gibson 2005.

The Cochrane review concluded that the effectiveness of intradiscal electrotherapy (IDET) remained unproven.

Agence d' Evaluation des Technologies et des Modes d'Intervention en Sante (AETMIS)
November 2005

In a report prepared for AETMIS, the recommendation was made, "to include this technology as an insured service conditional upon it being used by appropriately trained physicians in medical settings where continuous evaluation and research are conducted and upon the creation of clinical registries for evaluating its effectiveness in Québec." The evidence was considered weak, and at the time of the report it was offered in one private medical clinic in Montréal. Currently the service is not insured in Québec.

ECRI Target Database
June, 2007

The state of the evidence base for intradiscal electrothermal annuloplasty for discogenic pain was rated low for quantity, quality, consistency and robustness. Adverse events for this technology were not well documented. Reimbursement appears to be limited as several local Medicare carriers and major third-party payers deny coverage for the procedure.

3. Internal technology assessment

CMS performed an extensive literature search utilizing PubMed for randomized controlled trials (RCTs) and nonrandomized controlled trials, cohort or case-control studies, case series studies and systemic reviews evaluating the use of thermal intradiscal procedures. The literature search was limited to the English language and specific to the human population, but included studies conducted in all countries, including the United States.

Evidence for IDET came from two randomized controlled trials, one case control study, one prospective matched control study, twenty-three case series, two systematic reviews and one meta-analysis. Evidence for PIRFT came from one randomized controlled trial and one prospective randomized dosing trial. Evidence for biacuplasty came from one case series. Evidence for PDD came from eight case series. The sponsors of IDET and biacuplasty provided additional information which included: reviews, case reports, cadaver studies, animal studies, and investigator biographies.

Evidence Summary

Randomized Controlled Trials

IntraDiscal Electrothermal Therapy

Pauza K, Howell S, Dreyfuss P, et al. A randomized, placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. The Spine Journal 2004;4:27-35.

Pauza reported on 64 patients that were randomized to either IDET (37) or sham (27). The objective of the study was to see if IDET was better than placebo treatment for low back pain of at least six months duration.

Initial inclusion criteria included:

1. Age 18 to 65 years
2. Low back pain present for greater than six months duration
3. Failure to improve after at least six weeks of nonoperative care
4. Low back pain exacerbated by sitting or standing and relieved by lying down
5. A score less than 20 on the Beck depression scale
6. No surgical interventions within the previous 3 months
7. Less than 20% disc height narrowing on lateral plain film radiographs

Initial exclusion criteria included:

1. Previous lumbar spine surgery
2. Abnormal neurological examination other than ankle reflex changes
3. Radicular pain by history or examination
4. Structural deformities such as spondylolisthesis at the painful segmental level
5. Vertebral canal stenosis or scoliosis
6. Intervertebral disc herniations greater than 4mm
7. Sequestered intervertebral disc herniations
8. Concomitant cervical or thoracic pain greater than 2/10 on a VAS
9. Uncontrolled or acute medical illnesses
10. Chronic severe conditions, such as rheumatoid arthritis
11. Ambulatory dysfunction
12. Pregnancy
13. Workman's compensation
14. Injury litigation
15. Disability remuneration
16. Allergy to contrast media or drugs to be used in the intended procedure
17. Unwillingness to consent to the study

The study was conducted in a private practice in a small city in Texas that specializes in spinal pain. The authors stated, "Between September 2000 and April 2002, patients for the study were recruited from the practice of the senior author, from colleagues and by invitations in local and national television and print media." There were 4,523 enquiries, but 3,163 patients declined to be randomized or comply with protocol and 1,100 did not meet initial clinical inclusion criteria. This left 260 potentially eligible patients. The potentially eligible patients were screened with discography. The authors stated, "A patient was deemed to have discogenic pain if provocation of an intervertebral disc reproduced their accustomed pain within similar pressure ranges but provided that no pain was reported when adjacent discs were stimulated or during sham pressurizations." Directly after discography, computed tomography (CT) scan was obtained. The authors stated, "To be eligible for the study, patients had to have a posterior tear of the annulus fibrosus." Of the original 4,523 patients, 64 were eligible for the study.

Patients were randomized by computer-generated random numbers. Sham treatment patients had an introducer needle placed in position for treatment during conscious sedation. The principal investigator was unblinded at this point. Procedural noise and time passage were similar to the active treatment group. Only the active treatment group received the flexible catheter. If pain was produced during heating, fentanyl was administered. After heating, 1 cc of bupivacaine and cephazolin 56mg/cc or gatifloxacin 0.33 mg/cc were injected into the disc. Both groups were dispensed hydrocodone 10mg/acetaminophen 325mg for post operative pain, wore a lumbar corset for 6 weeks and participated in an exercise program from week six to 12. Exercise compliance was assessed by a blinded evaluator. Before treatment and at six months post procedure, the 10-point VAS, the SF-36, and the ODI were used to compare outcomes. It was not clear what the follow-up was between treatment and the six month visit, or exactly how soon before surgery the pretreatment measures were recorded. The window for six month follow-up was not defined. Outcomes were assessed by a blinded evaluator. The authors stated, "The primary objective of the study was to compare the improvement in pain and physical function between groups," so the statistical tests they chose were a group means comparison using a t test for continuous variables and the Fisher's exact test for categorical variables and frequency distributions. It was not stated that the assumptions of these statistical tests were met (such as homogeneity of variance between treatment groups or normal distribution of outcome/dependent measures). Other post-hoc analyses were conducted, including the proportion of patients at six months who obtained varying degrees of pain relief compared to pretreatment levels. Power calculations used 80% power to detect a difference of 2.0 and a standard deviation of 2.8. The authors admitted that they recruited fewer patients than planned and that the power was reduced from 80 to 60%, but that "60% power was enough to detect the significant differences reported." The Type I error (finding a treatment effect when a treatment effect does not actually exist) was not given.

Demographics were reported for 37 IDET patients and 27 sham patients, which was different than the number of patients in the final analysis. The mean age for both groups was about 40 years old. While it was stated that there were no relevant statistically significant differences between the groups at inception, 15% of sham treatment versus 8% of IDET treatment were unemployed because of back pain, with 81% of IDET patients working and 63% of patients in the sham group working. Baseline metrics of VAS, SF-36 by subscale, and ODI were reported. The authors commented, "In essence, the patients were reasonably healthy apart from having pain and slight to moderate disability in physical functioning, as seen both on the SF-36 and the Oswestry scale." Patient blinding was checked within one hour after treatment and was deemed to be adequate at that time. Intention to treat analysis was not done so only 32 patients in the IDET group are reported and 24 in the sham group (Five missing IDET patients: one died, one had poor catheter placement, one had a fractured leg, two had a new injury. Three missing sham group patients: one was non-compliant with follow-up, one had concurrent illness, one had a drug abuse problem and a compensation claim). See Table 1 for main outcomes reported.

Table 1 - Main outcomes of patients who underwent IDET or sham treatment

Outcome measure	IDET (n=32) Mean SD	Sham (n=24) MeanSD	P value*
VAS for pain (0-10)			

Outcome measure	IDET (n=32) Mean SD	Sham (n=24) MeanSD	P value*
Pretreatment	6.6 1.4	6.5 1.9	0.758
6 Months	4.2 2.6	5.4 2.7	0.089
Change	2.4 2.3	1.1 2.6	0.045
SF-36 Bodily Pain (0-100)			
Pretreatment	36 12	35 12	0.765

Outcome measure	IDET (n=32) Mean SD	Sham (n=24) MeanSD	P value*
6 months	53 19	44 20	0.085
Change	17 19	9 15	0.086
SF-36: Physical Functioning (0-100)			
Pretreatment	56 24	49 21	0.236
6 months	71 22	60 24	0.079
Change	15 27	11 17	

Outcome measure	IDET (n=32) Mean SD	Sham (n=24) MeanSD	P value*
			0.548
Oswestry Disability Scale (0-100)			
Pretreatment	31 10	33 11	0.485
6 months	20 12	28 15	0.023
Change	11 11	4 12	0.050
* p value calculated from t test			

Post-hoc analyses were done that defined absolute change as pain score being worse, same, improvement < 2.0, improvement > 2.0 and relative change as percentage of change (< 0%, 0 - 24%, 25 - 49%, 50 - 74%, 75 - 99%, 100%). The conclusion with this analysis was that there were statistically significant differences in favor of IDET. Another post-hoc analysis was presented that examined the two groups on the basis of baseline outcome measures. The authors concluded, "It emerged that IDET was significantly more effective for patients with pain scores less than 70 at inception and for patients with poor function or greater disability at inception." There was no controlling for the increased probability of a Type I error (finding a difference when in fact there is no difference) or rationale to the cut points.

The authors did not report analgesia use after treatment other than, "None of these patients resorted to any co-intervention or self-medication outside the postoperative analgesics and rehabilitation program that were prescribed." While they stated that both groups underwent a monitored postoperative rehabilitation program, exercise compliance was not reported. They did not report specifically any adverse events other than, "No patient had any adverse effects attributable to their treatment."

The authors concluded, "Nonspecific factors associated with the procedure account for a proportion of the apparent efficacy of IDET, but its efficacy cannot be attributed wholly to a placebo effect. The results of this trial cannot be generalized to patients who do not fit the strict inclusion criteria." Effect size was not given. The authors stated, "Indeed, for achieving greater than 75% relief of pain, the number needed to treat with IDET is 5."

Freeman B, Fraser R, Cain C, et al. A Randomized, Double-Blind, Controlled Trial Intradiscal Electrothermal Therapy Versus Placebo for the Treatment of Chronic Discogenic Low Back Pain. Spine 2005;30(21):2369-2377.

The industry supported trial of Freeman reported on 57 patients that were randomized to either IDET (38) or sham (19). The objective of the study was to test the safety of IDET compared with sham treatment for low back pain of at least three months duration. The selection of patients for the trial was based on advice from Saal and Saal, the inventors of IDET (Freeman, Fraser et. al. 2006).

Eligibility criteria included:

1. Minimum age 18
2. Candidate for IDET procedure at one or two levels
3. Symptoms of degenerative lumbar disc disease of at least three month duration
4. Failure to improve with a minimum of six week of conservative treatment (including pain medication and physical therapy)
5. Present with marked functional limitation
6. Sitting intolerance greater than standing intolerance
7. Present with predominant low back pain with or without referred leg pain
8. Negative straight leg raise and normal neurologic examination
9. The presence of degenerative disc disease on MRI with global disc degeneration or posterior or posterolateral annular tear evident
10. The presence of one or two level symptomatic disc degeneration as determined by provocative lumbar discography at L3-L4, L4-L5, L5-S1 and with an adjacent asymptomatic control disc
11. At the target level, the discogram and subsequent computed tomography scan should demonstrate contrast spreading to the outer annulus or beyond the confines of the disc
12. Must be willing to comply with follow-up as per the protocol

Exclusion criteria included:

1. Evidence of a large contained or sequestered herniation (small contained herniation is allowed)
2. Loss of more than 50% disc height at the target level
3. Severely disrupted disc (sufficient annular tissue is required for safe catheter placement)
4. Neurogenic claudication due to spinal stenosis
5. Three or more symptomatic lumbar disc levels
6. Previous back surgery at any level of the lumbar spine
7. Spondylolisthesis at a symptomatic disc level
8. Psychological disorders that may impact treatment outcome (e.g., severe depression, drug addiction)
9. Medical condition that could interfere with follow-up care or evaluation
10. Current injury litigation
11. Pregnant women
12. Failure to understand informed consent form
13. Participation in other studies of any kind

Study participants were chosen from consecutive patients of three spine surgeons if they satisfied eligibility criteria. Randomization occurred after catheter placement (both active and sham had flexible catheter placement) via sealed envelope by an independent technician who was responsible to covertly connect the catheter if the patient was to receive active treatment. All subjects followed a common rehab program, compliance was not mentioned. Patient evaluations occurred at six weeks and six months by an independent investigator. Outcomes measures were recorded at baseline and six months and included the VAS, low back pain outcome score (LBOS), ODI, SF-36, Zung Depression index, the modified somatic perception questionnaire, sitting tolerance, work tolerance, medication, and the presence of any neurologic deficit. Success was defined a priori as a composite measure: no neurologic deficit resulting from the procedure, an improvement in the LBOS of seven or more points, and an improvement in the SF-36 subscales of bodily pain and physical functioning of greater than one standard deviation from the mean. Sample size was calculated before the study and using a 2:1 allocation with 80% power, 75 patients were required. A chi squared test was planned for statistical analysis of the primary outcome and for continuous measures the t test was chosen, with ANCOVA (analysis of covariance) for analyses adjusted for the relevant baseline measures. Only 57 patients were enrolled after 25 months. The authors stated, "A request by the sponsoring company was made to pool our results with a U.S. randomized controlled trial on IDET that had been set up using a modified version of our protocol. This offer was declined because the studies were dissimilar."

Baseline demographics and multiple clinical characteristics were comparable. Mean age was about 40 with maximum age reported as 54 years. No co -morbidities were reported. For the IDET group, 50% were working with 10% on disability, whereas 63% of the sham group were working and none were on disability. Two subjects from the IDET group were withdrawn before the end of the study and excluded from the analysis. One was a technical failure and the other underwent fusion for increased pain. In the final analysis of 36 IDET patients and 19 sham patients, no subject in either treatment arm met the composite criteria for success. For some patients the SF-36 subscales did show improvement. For a change in physical functioning and change in bodily pain index greater than or equal to one standard deviation, 8.3% of IDET participants met this criteria and 15.8% of sham participants met this criteria. Mean improvement in the VAS was 0.57 units for the IDET group compared to 0.15 units for the sham group, with percentage of improvement for individuals not given (Freeman, Fraser et al. 2006).

Table 2 - Comparison of changes in scores at baseline and at 6 months

Variable	IDET (n= 36) Mean (95% CI)	Placebo (n= 19) Mean (95%CI)	Difference of Means (95%CI)	Pr > |t|
LBOS	-0.971 (-2.337, 0.394)	0.737 (-0.765, 2.238)	-1.708 (-3.824, 0.408)	0.111
	-1.314	0.842	-2.156	

Variable	IDET (n= 36) Mean (95% CI)	Placebo (n= 19) Mean (95%CI)	Difference of Means (95%CI)	Pr > |t|
ODI	(-4.171, 1.543)	(-6.149, 7.833)	(-8.369, 4.056)	0.489
ZUNG	-0.167 (-2.481, 2.148)	0.706 (-3.834, 5.246)	-0.873 (-5.302, 3.557)	0.693
MSPQ	0.286 (-1.533, 2.104)	0.177 (2.733, 3.086)	0.109 -3.036, 3.254)	0.945
SF-36 Physical functioning	2.624 (-2.675, 7.922)	1.579 (-6.416, 9.574)	1.044 (-8.045, 10.13)	0.819
SF-36 Bodily Pain Index	5.056 (-0.799, 10.91)	7.053 (0.963, 13.142)	-1.997 (-11.02, 7.031)	0.659

Results were analyzed by multiple subgroups at the request of the sponsoring company, Oratec, and no clinically important differences were found. Though analgesic use was not mentioned, it was mentioned in two of these subgroup analyses (no access to the data). One group analysis excluded subjects taking narcotic medication at baseline and the other excluded subjects taking eight or more panadeine forte tabs per day at baseline.

The authors reported that no serious adverse events in either arm of the study occurred, without defining serious adverse events. The authors also reported, "Transient radiculopathy (< 6 weeks) was reported in four study participants who underwent IDET and in one study participant who underwent the sham procedure."

The authors concluded that IDET was no more effective than placebo for the treatment of chronic discogenic low back pain.

Percutaneous Intradiscal RadioFrequency Thermocoagulation

Barendse G, van den Berg S, Kessels A, et al. Randomized Controlled Trial of Percutaneous Intradiscal Radiofrequency Thermocoagulation for Chronic Discogenic Back Pain. Spine 2001;26(3):287-292.

Barendse reported on 28 patients randomized to either radiofrequency thermocoagulation (13) or sham (15) treatment. Recruitment for the trial was from specialist's referrals to a university hospital of patients with chronic nonspecific low back pain for more than one year.

Exclusion criteria:

1. Patients with radiculopathies and other neurologic abnormalities
2. Younger than 30 or older than 65
3. Spinal stenosis
4. Spondylolisthesis
5. Multilevel burnt out disc lesions
6. Coagulation disturbances
7. Pregnancy
8. "initial "high" visual analogue score less than 5.0"
9. Diabetes mellitus
10. More than one pain syndrome

Patients had a diagnostic block of the dorsal rami to exclude zygapophysial joint pain. Then, discography with anesthesia was performed at L4-L5 and L5-S1 and only those patients who reported good pain relief or no pain 30 minutes after the procedure were selected for the study. If patients had more than one level that was positive they were excluded. Patients who met all the inclusion/exclusion criteria and who consented to participate were randomized to two treatment groups by computer program. The sham group was reported to be treated the same as the treatment group but no current was applied during their procedure. The treating physician was blinded throughout the procedure, with a disinterested third party applying the current after opening of the randomization envelope. Data were obtained by an investigator blinded for the allocation of the patient. Analgesic intake was monitored.

Radiofrequency lesioning was performed giving a 90-second 70°C lesion to the center of the disc. The ODI and the Dartmouth COOP Functional Health Assessment charts/World Organization of Primary Care Physicians chart was scored before treatment and eight weeks after treatment. Success was defined as at least a two point reduction on the VAS and at least a 50% pain reduction on global perceived effect. Patients judged to be a success were also assessed at three, six, and 12 months. Patients who failed treatment by this definition were removed from the study and subsequently offered different treatment options. The primary outcome was the percentage of successes at eight weeks. Success rate comparison included an odds ratio with 90% confidence interval calculated with a logistic regression model. Analyses adjusted for gender, age, duration of pain before treatment, average pretreatment pain intensity, and score after diagnostic nerve block. Secondary outcomes included differences between group changes in VAS score, ODI, use of analgesic tables, and COOP/WONCA chart (international version of Dartmouth COOP chart; WONCA = World Organization of National Colleges, Academies and Academic Associations of General Practices/Family Physicians) and their 90% confidence intervals. Analyses were performed unadjusted with a Student's t test and adjusted by using a linear regression model.

Between July 1994 and September 1996, 287 patients with chronic nonspecific low back pain were screened. Thirty-seven patients fulfilled all selection criteria, but only 28 entered the trial. Demographics are listed in Table 3.

Table 3 - Study demographics

Variables	Sham group (n=15)	Lesion Group (n=13)
Sex	5 Males, 11 females	5 males, 8 females
Age, mean(SD) yr	45.2 (8.4)	40.8 (7.5)
Months of pain, median(range)	38 (10-300)	60 (8-204)
Pretreatment VAS, mean(SD)		
VAS mean	5.5 (1.1)	6.5 (1.3)
VAS high	8.0 (1.3)	8.6 (1.1)
	3 (1-6)	4 (2-6)

Variables	Sham group (n=15)	Lesion Group (n=13)
VAS low		
No. of analgesic tablets per 4 days, Median(range)	5 (0-15)	3 (0-19)
ODI, mean(SD)	40.7 (9.5)	43.7 (11.6)
L4-L5 level of discogenic pain	6	4
L5-S1 level of discogenic pain	9	9

One patient who was allocated to sham therapy received an RF treatment, so analyses were performed with an intention to treat and as treated. Eight weeks after treatment, there were two treatment successes in the sham group and one in the lesion group. The adjusted and unadjusted odds ratio was 0.5 and 1.1, respectively (not significant). There were no statistically significant differences between the two groups in secondary outcome variables. It was reported that there were no complications during or after the procedure, though complications were not defined.

The authors concluded that percutaneous intradiscal radiofrequency thermocoagulation for 90 seconds at 70°C was not effective in reducing chronic discogenic low back pain.

Prospective Randomized Dosing Trial

Percutaneous Intradiscal RadioFrequency Thermocoagulation

Ercelen O, Bulutcu E, Oktenoglu T, et al. Radiofrequency Lesioning Using Two Different Time Modalities for the Treatment of Lumbar Discogenic Pain: A Randomized Trial. Spine 2003;28(17):1922-1927.

Ercelen reported a study of 39 patients with at least a two year history of chronic low back pain who had failed some kind of conservative therapy and were randomized into two treatment groups evaluating different durations of radiofrequency therapy. According to the authors, patients were included who had various conservative treatments for at least two years, had persistent pain and the qualities of their lives were severely affected (no further inclusion details were identified).

Exclusions were listed as:

1. spinal stenosis
2. instability
3. spondylolisthesis
4. diabetes mellitus
5. tumor infiltration
6. coagulation disorders
7. clinical radiculopathy
8. other neurologic abnormalities or systemic inflammatory diseases

Sixty patients had decreased signal intensity on T2-weighted images on MRI. The criterion for inclusion from this group was positive provocative discography. Out of sixty patients, 39 had positive discography and were entered into the study. Patients were randomized by computer into a group receiving radiofrequency lesioning an 80°C for 120 seconds (Group A, 20 patients) or 360 seconds (Group B, 19 patients). Note that one patient in group A had discitis and one patient in group B did not return for follow up and both were excluded from analysis (they were not counted as failures). Other adverse events were not listed. Patients were assessed with VAS by a nurse immediately after the procedure, at one and two weeks, and at one, three and six months after treatment. ODI was assessed before the procedure and at one and six months.

Patient characteristics were listed for 37 patients. The average age of both groups was about 40. Gender, level of discogenic pain, VAS and ODI were similar at baseline. The level of discogenic pain was either L4-L5 or L5-S1. While patients were evaluated for radial and/or circumferential tears, they did not include these as followed parameters. While early scores (one month follow-up or less) showed improvement, at six months there were no statistical differences between the final (six months) and the pretreatment VAS and ODI values in both groups ($P > 0.5$). Also, at six months follow up, there were no statistical differences between the two groups in ODI or VAS. The authors concluded, "The results of this study indicate that the disc radiofrequency lesioning seems to provide short-term relief for a period of 1 month. But this effect cannot be claimed to be significant, because there was no control group to compare. Because the response to pain relief decreased gradually after 1 month, this method is unacceptable as a long -term modality."

Case Control Studies

IDET

Bogduk N, Karasek M. Two-year follow-up of a controlled trial of intradiscal electrothermal annuloplasty for chronic low back pain resulting from internal disc disruption. The Spine Journal 2002;2:343-350.

Karasek M, Bogduk N. Twelve-Month Follow-up of a Controlled Trial of Intradiscal Thermal Anuloplasty for Back Pain Due to Internal Disc Disruption. Spine 2000;25(20):2601-2607.

Bogduk reported on 53 patients with back pain, 36 of whom were treated with IDET and 17 of whom, due to insurance denial, were treated with other types of treatment. Karasek reported the 12 month follow-up of this group, while Bogduk reported the two-year follow-up. Patients were recruited from a single site private practice referral clinic. Recruitment occurred between May 1998 and November 1998, where 150 consecutive patients were seen in whom back pain had been present for at least three months with no evidence on history, clinical exam or imaging of disc prolapse, neurological disease, tumor or infection. It was stated that a number of conservative measures had been attempted, but did not offer a specific protocol. Forty of these patients were excluded due to multilevel disc degeneration on MRI or clinical features that suggested zygapophysial joint pain, muscle pain or sacroiliac pain. One hundred and ten patients then underwent discography and subsequent CT.

Study inclusion criteria included:

1. Positive provocative discography. For a disc to be positive, infiltration of the disc had to reproduce the patient's pain whereas infiltration of adjacent discs did not.
2. The painful disc exhibited a radial fissure reaching at least the outer third of the annulus fibrosus but with the outer perimeter of the annulus being intact, without communication with the epidural space.

Exclusion criteria included:

1. Less than 80% of expected normal disc height.
2. Significant comorbidity that would confound the assessment of outcome.
3. Previous lumbar fusion.
4. Anatomical abnormalities that would interfere with the procedure.

Of the 110 who met the previous criteria, 53 met the above inclusion criteria. Insurance carriers were contacted and authority was obtained in 36 and denied in 17. The comparison group of 17 "proceeded to a rehabilitation program" that had been the manner of treatment for that practice for patients with discogenic pain. No further details about the program were given. For the treatment group, the electrode was maneuvered into various positions in an attempt to heat the posterior and posterolateral annulus in the region of the radial fissure to a temperature that the patient could tolerate (80° – 90°C) as much as possible. Cefazolin was administered intravenously and intradiscally. Outcome measures were the VAS, return to work and use of opioids analgesics, or "other major interventions." Measures were obtained before treatment and at three months after treatment in both groups, and then only in the IDET group at six, 12 and 24 months. The 17 patients in the comparison group left the practice so could not be followed; however, where possible, "they were contacted to determine their status at 12 months and at 24 months." Success was defined ad hoc as at least 50% reduction in pain, that patients remained or retuned to work, and no longer required opioids for their pain (where they defined opioids as morphine, hydrocodone, or drugs of similar potency, so other analgesics including small quantities of codeine were allowed).

Demographics were reported to be similar for treatment and comparison groups. Median age for the treatment group was 39 years (range 31-50) and 45 years (range 34-49 years) for the comparison group. The median duration of back pain was about 30 months for both groups (interquartile range 12-72 for comparison group, 14-70 for the treatment group), with a VAS for pain of eight (interquartile range of 5-8 for the comparison group and 7-9 for the treatment group). Discs that were judged to be painful included both single level discs (L1-2, L2-3, L3-4, L4-5, L5-S1) and two level discs (L3-4, L4-5; L3-4, L5-S1; L4-5, L5-S1). Interestingly, eight of 17 in the comparison group had workers compensation or motor vehicle accident claims, and 17 of 36 in the treatment group had claims. The results showed little change in median VAS (7.5 at 12 and 24 months) for the comparison group during the 24 month follow-up, though five patients were lost to phone follow-up at 12 months (three received IDET, one died, one refused to provide data) and two more were lost at the 24 month follow-up (could not be contacted). The treatment group maintained a statistically significant decrease in median VAS (3.5 at three months; 3.0 at six, 12, and 24 months) through-out the 24 month follow-up (one patient lost to follow-up at 12months). VAS scores were also examined as percentage change in VAS at three, 12, and 24 months, which the authors referred to as categorical outcomes. The authors reported, "These categorical data, however, are somewhat illusory, because the patients with particular degrees of recovery at one time period are not necessarily the same patients with those degrees of recovery at a following period." Information of individual VAS scores by follow-up time was provided graphically but not in table form. The graph demonstrated variability in the scores but not necessarily sustained improvement. For the comparison group, only one patient returned to work who was initially not working and of 10 patients working before treatment, three ceased work. They reported that seven in the comparison group still used opioids (follow-up time not given), that five had stopped but four started using opioids. For the treatment group of 35 patients, of 16 patients not working, nine returned to work. Twelve still used opioids at two years. Four patients underwent fusion without subsequent relief of pain. The authors noted that compensation status (i.e., worker's compensation) was not a determinant of outcome. Given the criteria that the authors defined as success, only one patient in the comparison group met these criteria – though this patient attributed the resolution of her back pain to a hysterectomy that she had at 12 months into the study. At 24 months, the treatment group was said to have a 54% (19 of 35) success rate, though from the global outcome table it appears to be 51% (only 18 of 35 met the no use of opioids criteria). The authors stated that 20% of patients treated with IDET had complete relief of pain, combined with return to work or remaining at work, and no use of opioids, based on the 24 month assessment. The authors concluded, "It is not universally successful, but 54% of patients can reduce their pain by half, and one in five patients can expect to achieve complete relief of their pain."

Prospective Matched Control Study

Kapural L, Hayek S, Malak O, et al. Intradiscal Thermal Annuloplasty Versus Intradiscal Radiofrequency Ablation for the Treatment of Discogenic Pain: A Prospective Matched Control Trial. Pain Medicine 2005;6(6):425-431.

Kapural matched 42 patients for age, sex, weight, smoking history, manual labor, and number of intervertebral discs treated. However, the authors stated that 21 had radiofrequency and 28 had IDTA which included seven patients that were unmatched. Mean age of patients was 42 years. Co-morbidities other than smoking were not listed. The authors stated, "The study was explicitly a head-to-head comparison of two techniques, by an operator experienced with both. The hypothesis was simply that outcomes would be no different." Single center-single physician performed all procedures but was not blinded, nor was the patient or outcome assessor blinded. Inclusion criteria were low back pain unresponsive to conservative treatment for greater than six months, no evidence of compressive radiculopathy, no prior surgery, disc height at least 50% of adjacent non-degenerated control disc, no evidence of disc herniation, no signs of lumbar stenosis, no psychological issues, evidence of single-level or two-level disc disease at MRI and positive provocation discography. Exclusion criterion was worker's compensation. The IDTA group had 90°C maintained for 4 minutes. The PIRFT group had 55°C for four minutes, 60°C for five minutes and 65° C for five minutes. There was no information about co-interventions in either group. Pain was rated by VAS and disability was assessed by the Pain Disability Index (unclear if validated in this population) at 12 months. Results included VAS pain score decreased from 7.4 +/- 1.9 before IDTA to 1.4 +/- 1.9 at one year follow-up while for PIRFT VAS scores decreased from 6.6 +/-2.0 before to 4.4 +/-2.4 at one year. Individual VAS scores were not reported.

Table 4 - The mean pain disability index (PDI) differences

Time	Estimated mean difference in PDI (IDTA-PIRFT)	Lower level 95% CI	Upper level 95% CI	P value
Preprocedure	7.2	-3.0	17.4	0.16
2 weeks	- 0.95	-11.2	9.2	0.85
2 months	-5.2	-15.4	5.0	0.31

Time	Estimated mean difference in PDI (IDTA-PIRFT)	Lower level 95% CI	Upper level 95% CI	P value
3 months	-17.3	-27.5	-7.1	< 0.001
6 months	-16.8	-27.0	-6.6	0.001
9 months	-24.2	-34.4	-14.0	< 0.001
1 year	-21.8	-32.0	-11.6	< 0.001

There was no mention of adverse events, patient follow-up numbers, or who was included in the follow-up tallies (for instance, 28 patients received IDTA; however, were all included in follow-up?). The authors concluded that, "IDTA appears to be more efficacious than RFA based on PDI and VAS scores measured at one year following procedure."

CASE SERIES

Thirty-two case series are summarized in Appendix B. A table of the case series precedes the summary.

Systematic Reviews of IDET and PIRFT

Andersson GB, Mekhail NA, Block JE. Treatment of Intractable Discogenic Low Back Pain. A Systematic Review of Spinal Fusion and Intradiscal Electrothermal Therapy (IDET). Pain Physician 2006;9(3);237-248.

A company-sponsored 2006 systematic review was done that included 18 IDET articles categorized by the authors thusly: 2 randomized controlled trials, 2 non-randomized controlled trials, "11 before-after trials", and 3 case series. These trials were included: Pauza et al. 2004; Freeman et al. 2005; Karasek and Bogduk 2000; Bogduk and Karasek et al. 2002; Derby et al. 2000; Saal and Saal 2000; Saal and Saal 2000; Singh 2000; Welch et al. 2001; Gertzen et al. 2002; Saal and Saal 2002; Spruit and Jacobs 2002; Lutz et al. 2003; Kapural et al. 2004; Mekhail and Kapural 2004; Endres et al. 2002; Cohen et al. 2003; Freedman et al. 2003. They did a historical comparison using selected fusion articles. The authors concluded, "The IDET procedure appears to offer sufficiently similar symptom amelioration to spinal fusion without the attendant complications." None of the studies included in this systematic review were actually head to head comparative studies of the two procedures.

Urrutia G, Kovacs F, Nishishinya MB, Olabe J. Percutaneous Thermocoagulation Intradiscal Techniques for Discogenic Low Back Pain. Spine 2007;32(10):1146-1154.

This systematic review was based on a literature search up to 2005. The methodological quality was independently assessed following the criteria recommended by the Cochrane Back Review Group. Six studies were included: Barendse et al. 2001; Bogduk-Karasek et al. 2002; Ercelen et al. 2003; Freeman et al. 2005; Kapural et al. 2005; Pauza et al. 2004. Urrutia's systematic review focused on IDET and PIRFT as the two percutaneous thermocoagulation intradiscal techniques to treat discogenic back pain. The results from the RCTs showed that PIRFT was not effective for the treatment of discogenic low back pain. For IDET, one RCT showed a positive effect only on pain severity, but the second and best quality RCT showed no effect on any variable. Urrutia noted, "… potentially serious adverse effects have been reported." The authors concluded, "The available evidence does not support the efficacy or effectiveness of percutaneous thermocoagulation intradiscal techniques for the treatment of discogenic low back pain."

Meta-Analysis of IDET

Appleby D, Andersson, G, Totta M. Meta-Analysis of the efficacy and Safety of Intradiscal Electrothermal Therapy (IDET). Pain Medicine 2006;7(4):308-316

A company-sponsored 2006 meta-analysis was done that included 17 articles. These trials were included: Pauza et al. 2004; Bogduk and Karasek 2002; Saal and Saal 2002; Wetzel et al. 2002; Lutz et al. 2003; Derby et al. 2000; Spruit et al. 2002; Gerszten et al. 2002; Singh 2000; Freedman et al. 2003; Lee et al. 2003; Mekhail et al. 2004; Kapural et al. 2004; Cohen et al. 2003; Endres et al. 2002; Webster et al. 2004; Davis et al. 2004. By the author's analysis, the mean improvement in VAS score was 2.9 points, 21.1 points on the SF-36 physical function score, 18 points on the SF-36 bodily function scale, and seven points on the ODI scale. The authors concluded, "Although variation exists in the reported outcomes among the various studies of the IDET procedure, the pooled results of the published studies provide compelling evidence of the relative efficacy and safety of the IDET procedure."

Adverse events

While there is no comprehensive database of adverse events for TIPs, several case reports and a review gave indications of possible events. In 2007, Kapural and Cata reviewed the complications of percutaneous techniques used in the diagnosis and treatment of discogenic lower back pain. They provided a list of these possible complications:

Infectious
Discitis
Epidural abscess

Vertebral osteomyelitis
Subdural empyema
Bacterial meningitis
Neural
Cauda equine syndrome
Nerve root damage – causalgia
Acute disc herniation
Allergic/immune hypersensitivity
Dye-induced anaphylaxis
Urticaria
Vascular
Retroperitoneal bleeding
Intramuscular hematoma
Others
Probe-electrode fracture
Muscle spasm

Diagnostic tests for thermal intradiscal treatments include provocative discography, so the risks of this procedure must be considered. The reported discography complication rate ranges from 0 to 2.5% (Kapural and Cata 2007). Discitis, epidural abscess and bacterial meningitis have all been reported (Kapural and Cata 20027). Acute lumbar disc herniations have also been reported (Kapural and Cata 2007). For IDET, Kapural and Cata suggested a reported range of 0% to as high as 10%, though one series reported 15% (Cohen et al. 2003). Davis was reported to have had one episode of discitis out of a case series of 44 patients (Davis, Delamarter et al. 2004). Orr reported a patient who underwent IDET at another center where the catheter tip that broke off inside the disc space had migrated to an intradural position that lead to a sensory neuropathy that improved but did not resolve after removal (Orr and Thomas 2005). Boswell reported a patient who underwent attempted discography and IDET that was complicated by at least two lumbar dural punctures (Boswell and Wolfe 2004). Post procedure, the patient developed severe back pain and then intractable seizures and coma. The patient could not be resuscitated and expired. It was concluded that the patient succumbed from an unintentional dose of intrathecal cefazolin which was in the contrast agent used to confirm needle placement (Boswell and Wolfe 2004). Orr stated, "The rationale that this procedure is justified because it is low risk and relatively noninvasive may need to be reassessed" (Orr and Thomas 2005). Hsia reported on a patient who experienced cauda equine syndrome from IDET after the catheter was inappropriately placed in the spinal canal (Hsia, Isaac et al. 2000). Six months post procedure the patient continued to require daily urinary self-catheterization and had bowel incontinence (Hsia, Isaac et al. 2000). About IDET Hsia noted, "This population may, in fact, not benefit from expensive or aggressive therapies." Ackerman as well reported a patient who developed cauda equina syndrome after IDET (Ackerman 2002). He noted that both cases of cauda equina were not reported by the treating provider (Ackerman 2002). Ackerman stated, "The IDET procedure is relatively new, and complications possibly related to it may not be readily reported because of potential litigation." Cohen reported on a patient who had a giant herniated disc following IDET (Cohen, Larkin et al. 2002). The patient proceeded to undergo lumbar fusion for pain and radicular symptoms. Scholl and Djurasovic each described a case of vertebral osteonecrosis related to IDET (Scholl, Theiss et al. 2003; Djurasovic, Glassman et al. 2002). Djurasovic's report described a patient who developed vertebral body osteonecrosis associated with the use of IDET (at another clinic) which led to incapacitating back pain that required surgical fusion (Djurasovic, Glassman et al. 2002). For discTRODE, there were no complications published in three studies and for intradiscal biacuplasty, out of about 100 cases, only a few patients reported transient back pain.

4. Medicare Evidence Development and Coverage Advisory Committee (MedCAC) Meeting.

CMS did not hold a MedCAC meeting on this topic.

5. Evidence-based guidelines

CMS identified three evidence based guidelines that addressed TIPs.

The American Society of Interventional Pain Physicians (ASIPP) guideline *Interventional Techniques: Evidence-based Practice Guidelines in the Management of Chronic Spinal Pain* (Boswell, Trescot et al. 2007) included a review of both IDET and radiofrequency posterior annuloplasty (RFA) for the treatment of discogenic pain from internally disrupted intervertebral disc as an alternative to major surgical intervention. This represented an update of previous guidelines put out by ASIPP. In the evaluation of these procedures, less than six months was equated to short term relief and six months or more was equated with long term relief.

In reference to IDET, the authors stated, "…the mechanism of action of IDET has not been established." Some of the assumptions of mechanism of action proposed in the guideline were that heating the annulus may serve to strengthen the collagen fibers, seal fissures, denature inflammatory exudates, or coagulate nociceptors. The review of the evidence for IDET included one positive randomized trial, one negative randomized trial, seven positive prospective evaluations and two negative reports. The authors evaluated the level of evidence for IDET as moderate for managing chronic low back pain.

For the RFA procedure, also identified by the name of the device (discTRODE), the authors evaluated the level of evidence as limited for short-term improvement, and indeterminate for long-term improvement in the management of discogenic low back pain. The studies identified for RFA were two prospective evaluations.

For PDD, the authors evaluated the evidence as limited for short- and long-term relief.

The *European guidelines for the management of chronic nonspecific low back pain* (Airaksinen, Brox et al. 2006) included a review of intradiscal radiofrequency thermocoagulation (IRFT) and IDET. The authors identified that the diagnosis of IDD was surrounded by controversy. In addition, the effect of IDET was not well understood.

The authors summarized the evidence as follows.

- "There is conflicting evidence that procedures aimed at reducing the nociceptive input from painful intervertebral discs using either IRFT or IDET, in patients with discogenic low back pain pain, are not more effective than sham treatments (level C).
- There is limited evidence that RF lesioning of the ramus communicans[2] is effective in reducing pain up to 4 months after treatment (level C)."

The recommendation for these procedures was stated as;

"We cannot recommend the use of Intradiscal radiofrequency, electrothermal coagulation or radiofrequency denervation of the rami communicans for the treatment of either nonspecific or "discogenic" low back pain."

The International Spine Intervention Society (ISIS) guideline, *Practice Guidelines Spinal Diagnostic & Treatment Procedures* edited by Nikolai Bogduk (2004) on behalf of ISIS standards committee, included a chapter on IDET but did not address other thermal intradiscal procedures. The ISIS guideline categorized IDET as an established procedure which it defined as "…those procedures for which there is reasonable, if not abundant, evidence of validity and utility, or efficacy; or procedures which, although lacking strong evidence, are nonetheless commonly practiced and for which there are no alternative procedures." While it did not identify IDET as one of the latter, discography was listed as such.

The guideline did not specifically categorize the strength of the evidence but did make reference to a number of published articles on IDET some of which were authored by members of the ISIS standards committee chaired by Kevin Pauza, MD. It was stated that, "The present Practice Guidelines do not pretend to be a systematic review of the literature concerning the various procedures addressed." However, they went on to state that the Standards Committee "endeavored to remain faithful to the rules of evidence." Rather than utilizing electronic literature searches, the Committee relied on personal libraries of authors and other members with experience in the procedures.

The guidelines provided a history of IDET as controversial due to the lack of controlled studies and the financial interests of persons conducting the initial studies. It identified the contentious rationale that was put forth as the mechanism for action and the lack of evidence to support any of the contentions. Both randomized controlled trials were referenced (the Freeman et al. study which was referenced as Fraser et al. and the Pauza et al. study). One study showed no difference in effect from the treatment group to sham control group (Freeman et al.) and the other study showed no significant differences between groups for mean scores for pain and physical function, but with significantly better Oswestry disability scores for the IDET group (Pauza et al.). The efficacy of the IDET procedure was identified as modest.

The guideline stated that the indications for IDET differed since the operators used different criteria, however all concurred on the diagnosis of discogenic pain determined by discography. The differences between the operators were identified as the diagnostic criteria for a positive discogram, preservation of disc height and the use of CT-discography. The need for CT-discography was identified as being the most contentious issue. It was also stated that while the literature points to application of stringent patient selection criteria for internal disc disruption to achieve the best long-term outcomes, other studies showed comparable outcomes "irrespective of differences in inclusion criteria."

The guideline stated, "Which criteria should be applied remains a matter of operator-choice. The ideal indications for IDET have not been established." Numerous contraindications were listed and with respect to patient selection it was stated, "Patients suitable for IDET should be ones who satisfy the diagnostic criteria for discogenic pain or for internal disc disruption, and who do not exhibit any of the contraindications. In essence, they will be patients with back pain, with or without somatic referred pain, free of co-morbidity that might interfere with the safe execution of the procedure or its outcome."

6. Public Comments

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

Initial Public Comments

CMS received 84 comments during the initial 30 day public comment period. Four national professional societies provided comments. One comment was submitted by a manufacturer of a thermal intradiscal system. Sixty-two comments were identified as being from physicians (three of which were on behalf of two state professional societies), ten comments were from employees of physician practices (eight were identified as employees of the same physician practice) and seven comments were from the general public. The complete text of these comments is available on the CMS website at http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=215 . Two comments were not posted to the web because they contained personal health information. The summary of the initial public comments can be found in the proposed decision memorandum at http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=215 .

Public Comments on Proposed Decision Memorandum

CMS received a total of thirty-six comments on the proposed decision for TIPs. Three comments were from national professional societies representing nine societies. Twenty-four comments were identified as being from physicians (one as representative of a state professional society, six were form letters provided by ASIPP web site). Three comments were from manufacturers. One comment was from a potential patient for TIPs. One comment was from a national health insurance company. The complete text of the comments is available on the CMS website at http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=215 .

Three commenters disagreed with our decision and supported coverage for TIPs in general (one specifically mentioned laser themodiscoplasty). Twenty-one commenters disagreed with our decision and supported coverage for IDET. One commenter disagreed with our decision and supported coverage for IDET and biacuplasty. Five additional commenters requested that CMS remove biacuplasty from this NCD until more trial evidence is available and two of these commenters supported non-coverage of IDET or older technologies. Two commenters supported coverage for PDD. One commenter requested that pulsed holmium laser intradiscal procedures be excluded from this NCD. One commenter supported the CMS decision.

A. National Professional Societies

CMS received three comments from national professional societies. Two comments were from the American Society for Interventional Pain Physicians (ASIPP) and the other comment was from eight societies (North American Spine Society (NASS), American Society of Anesthesiologists (ASA), the American Society of Spine Radiology (ASSR), the American Academy of Pain Medicine (AAPM), the Physiatric Association of Spine, Sports, Occupational, and Rehabilitation Physicians (PASSOR), the American Academy of Physical Medicine and Rehabilitation (AAPMR), (ASIPP), and the International Spine Intervention Society (ISIS)).

There were two individual comments from ASIPP. One comment from ASIPP provided comments with regard to IDET. The society commented that the evidence synthesis by CMS focused on randomized trials and to some extent prospective evaluations and the "….results failed to translate specifically into the Medicare population." While the society agreed with many of the drawbacks identified in the CMS analysis, they pointed out that IDET is only suitable in populations below 65, rather than 65 or older. The society concluded from an unofficial survey that 50% to 65% of interventional pain management Medicare patients are below 65 years of age.

Response: There is no convincing evidence that IDET improves health outcomes in any patients, regardless of age.

The society felt that one of the drawbacks of the CMS analysis was the inclusion of studies outside the United States.

Response: CMS considers all quality publications; however, we do limit our literature searches to articles in English. Bias in evidence consideration can lead to erroneous results. However, even if evidence from studies outside the United States were excluded, the conclusions do not change.

The society commented that in the past CMS has focused on practical clinical trials rather than only randomized trials. They felt trials measuring effectiveness should be given more importance than explanatory trials measuring efficacy. They felt pragmatic or practical trials were best designed to provide results of benefit of a treatment. They further stated that pragmatic trials addressed the lack of placebo group with a treatment response accounting for the total difference between two treatments as well as associated placebo effects. They felt that this treatment response would best reflect the likely clinical response in actual clinical practice.

Response: CMS examines both explanatory and pragmatic trials. Appropriate clinical trial design can be challenging but is very important. Raynard S. Kington, Deputy Director of the National Institutes of Health stated, "Appropriate clinical trial design is vital to ensuring scientific validity, to providing societal benefits from knowledge gained, and to upholding ethical principles in human subjects research" at the NIH 2005 conference, Considering Usual Medical Care in Clinical Trial Design: Scientific and Ethical Issues. Explanatory trials are those which measure the benefit of a treatment under ideal conditions, generally using carefully defined subjects in a research clinic. Pragmatic trials are considered those trials that better reflect what occurs during routine practice. If the commenter is suggesting that the TIPs' case series are pragmatic trials, to equate pragmatic trials with case series which lack a comparison arm is incorrect. Therefore, case series do not demonstrate effectiveness in the treatment of low back pain. The majority of published evidence on TIPs is in the form of case series.

The society commented on the hierarchy of evidence and referenced an ARHQ publication (West et al. 2002) on the synthesis of evidence and the U.S. Preventive Services Task Force (USPSTF) hierarchy of evidence chart (Berg and Allan 2001). The society commented that they believed that CMS should consider using the USPSTF standards. They felt that based on this evidence synthesis IDET would fall into Level II-2 and would provide a strong 1C/strong recommendation based on Guyatt's criteria (Guyatt, Gutterman et al. 2006).

Response: CMS' general approach to the evaluation of evidences is included as Appendix A and is generally consistent with evidence assessment by other well-respected groups such as USPSTF. Level II-2 is not the USPSTF standard recommendation language but would refer to the level of evidence. Guyatt's evidence grading recommendations take into account the methodological quality of supporting evidence and the benefit vs. risk and burdens. CMS disagrees with the level of evidence for IDET (there is at least one well designed RCT) and the IDET recommendation based of Guyatt's criteria, and notes that for evidence on IDET to meet Guyatt's Grade of Recommendation classification of 1C/strong, the benefits would have to clearly outweigh risk and burdens. IDET does not meet this standard.

The society commented that CMS needed to consider the balance in costs and benefits. They stated that IDET was a procedure with a much lower cost and provided significant improvement in the quality of lifecost-effective.

Response: CMS does not consider cost in making national coverage determinations under §1862(a)(1)(A) of the Social Security Act.

The society provided comment on the role of evidence-based medicine. They felt that CMS and other advocates of evidence-based medicine "…should want clinicians and consumers to pay attention to the best findings from health care research that are both valid and ready for clinical application." They pointed out that critics of evidence-based medicine do not feel there is any evidence that evidence-based medicine provides better medical care (Goodman 1999). They felt it is essential to develop a middle ground by harmonizing evidence-based medicine and other approaches. They commented that we "…should adhere to the fundamental principles in evidence-based medicine: 1) is the research valid? 2) are the best findings from this research available? 3) is this health care research ready for general application? 4) to whom and how does one apply valid and ready evidence from health care research?" They felt that EBM included three dimensions – clinical training and experience, judicious integration of science and patient preferences and values. They further stated that scientific evidence only constituted one-third of the issue and needs to be integrated judiciously.

Response: CMS encourages high quality medical care by providers and does not attempt to supplant the independent judgment of clinicians responding to particular clinical situations. For the beneficiary, CMS believes informed consent is important for patient decision making. The Institute of Medicine (IOM) issued a report, Crossing the Quality Chasm (2001,) to urge improvement in the way health care is delivered in this country. The IOM emphasized that patients should receive care based on the best available scientific knowledge and should not vary illogically from clinician to clinician or from place to place. CMS believes that the judicious integration of scientific evidence is important for high quality patient care. We do consider the judgment of practitioners, but believe, in general, it warrants less weight.

The society requested that CMS change its decision and include coverage only for IDET in patients under the age of 65 utilizing strict criteria.

Response: CMS concludes that the evidence does not demonstrate improved outcomes for IDET in patients under 65 years as well as for those over 65 years. There is no convincing evidence IDET works for any group of patients.

The second individual comment from ASIPP requested that CMS exclude disc biacuplasty from the NCD for TIPs and leave assessment of coverage for disc biacuplasty to the discretion of local contractors since the clinical evidence on biacuplasty is still being developed. The society opined that disc biacuplasty offered a new and promising technological approach to treatment of CLBP. They stated there were technological and clinical differences between disc biacuplasty and other TIPs and that IDET was unable to achieve the same therapeutic results as disc biacuplasty. They also stated that disc biacuplasty differed from IDET in the procedural technique. They stated that IDET "…is inherently risky as it involves invasion of more disc material, increasing the likelihood of complications." They felt that the technique for biacuplasty potentially reduced complications.

Response: CMS agrees with the statements regarding the risks of IDET and we have stated that complications of this procedure may be underreported. CMS recognizes that there are some differences among the techniques and devices employed in TIPs; however, we believe the various techniques utilized for TIPs use the same function and seek the same desired outcome (the application or creation of heat and/or disruption within the disc to relieve pain) and should be grouped under one NCA. The biacuplasty technique utilizes radiofrequency energy to produce heat from two internally cooled probes which delivers heat to a larger area within the annulus. The Baylis Trans Discal System was cleared by the FDA in January of 2007. To date there is one small published case series for this technique and major limitations of the study are identified by the author. The evidence is not adequate to determine that biacuplasty is reasonable and necessary under §1862(a)(1)(A) of the Social Security Act. If the trials that are under way for biacuplasty provide new evidence of benefit for the Medicare population, CMS will, upon request, open this NCD for reconsideration.

There was a combined comment from NASS, ASA, ASSR, AAPM, PASSOR, AAPMR, ASIPP, and ISIS in which they stated that they agreed with CMS that for Medicare patients over the age of 65 that there was no evidence that TIPs are effective in such individuals. However, they felt that the CMS decision has disconcerting implications that reach beyond the funding of care for the elderly. They cited the propensity for insurers and others to adopt CMS decisions inappropriately and with-out qualification to non-Medicare patients.

Response: Our NCD process is based on a thorough review of the evidence and how that evidence relates to the Medicare population including disabled Medicare beneficiaries. Our analysis and decisions are available to the public. The conclusions and coverage determinations are for our Medicare population. Although CMS is aware that other payers may choose to follow Medicare coverage policy, this is not a consideration in the NCD process. We note that for TIPs many commercial health insurance companies have already performed their own independent review of these procedures and many came to a conclusion of non-coverage for their patient population.

The societies felt that CMS had raised the standard of evidence required in evaluating IDET by only evaluating RCTs that included the Medicare age-group. They felt that this standard had not been applied in other NCDs for spine care.

Response: While each NCD is different, RCTs generally receive a higher weight in the consideration of the evidence. CMS completed a thorough review of the published clinical evidence which included RCTs, a prospective randomized dosing trial, case control studies, a prospective matched control study, thirty-two case series, as well as systematic reviews and meta-analysis and numerous technology assessments. We also considered the public comments. We believe our decision is consistent with and supported by the evidence.

The societies commented that TIPs were not a singular modality. They felt that the procedures are distinguished by the mechanism of heat generation and the placement of the electrodes within the disc. They felt that, "IDET specifically targets the annulus fibrosus, where it has the potential to affect fissures and the nerve endings of the disc, provided the heating element is accurately placed."

Response: CMS recognizes that there are some differences among the techniques and devices employed in TIPs; however, we believe the various techniques utilized for TIPs use the same function and seek the same desired outcome (the application or creation of heat and/or disruption within the disc to relieve pain) and should be grouped under one NCA.

The societies felt that for IDET ten observational reports demonstrated improved outcomes that are maintained for two years and a controlled trial showed that these outcomes cannot be wholly attributed to placebo effects. They commented on the necessity of appropriate selection criteria.

Response: There are no trials with a control that confidently demonstrate that IDET is different than placebo. The nonrandomized trials have major sources of uncontrolled confounding, and do not demonstrate a sustained response, as evidenced by the comment of an author, that patients with particular degrees of recovery at one time period are not necessarily the same patients with those degrees of recovery at a following period. The remaining five observational studies are case series, and are not designed to determine whether a treatment works or not. Four case series studies demonstrate poor outcomes. The totality of the evidence reviewed does not show that IDET is reasonable and necessary to threat chronic low back pain.

The societies felt that selection criteria that determine the use of IDET should be based on physiologic characteristics of a painful disc, not age or Medicare status.

Response: No specific physiologic characteristics of a painful disc in patients with low back pain have been reliably validated. There is no convincing evidence that TIPs are effective in any patient population.

The societies requested that any limitations to the coverage of IDET for Medicare patients be based on the application of recommended selection criteria and not by demographic classification.

Response: There is no convincing evidence IDET works for any group of patients.

B. General Public Comments

A number of commenters felt that CMS disregarded the comments supporting coverage for IDET from physicians and societies most familiar with the procedure (this statement was also in the ASIPP supplied form letter). A statement was also made that, "If there was a large coterie of physicians with strong negative views about the effectiveness of IDET, surely they would have voiced their disapproval in this forum."

Response: CMS uses the public comments to inform its final decision. Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. Ultimately, the decision of whether an item or service is reasonable and necessary is based on the evidence. The absence of negative public comments concerning a procedure does not necessarily mean that all other physicians and other practitioners endorse the product or service for a particular use, as other factors may influence the submission of comments.

One commenter made accusations that CMS took quotes and statements out of context, wrote the decision memorandum in a biased format to support an opinion to deny access to these therapies, misrepresented authors views. There were additional statements from this commenter that CMS discredited the Anderson systematic review by stating it was not a head to head comparison and discounted a meta-analysis because we provided information about a funding source. This commenter stated, "Whether we like it or not in the world we live today almost all research into new technology is sponsored by companies or else it would not be done. Medicine has become a business." A second commenter stated that CMS used quotations from individuals with known bias against invasive back treatments and the value of discography.

Response: We strongly disagree with these comments. We believe we fairly quoted authors and provided all references. CMS presents the evidence in a transparent fashion. The information regarding the Andersson review was to inform the readers. The systematic review by Andersson had significant methodological flaws which decreased it weight. Historical comparisons, such as the Anderson review, are difficult to draw conclusions from as it is impossible to discern if the patient populations are similar. Therefore, less weight is given to historical comparisons if we can not discern that the patient populations were consistent over time. CMS does not automatically put a lesser weight on a study because it is industry sponsored. However, it is possible that industry sponsored research is more likely to favor the industry sponsor's product in comparison to non-industry sponsored research. We consider potential bias in weighting evidence.

One Commenter from a large health insurance company congratulated CMS on a very thoughtful and comprehensive review of the topic. The commenter stated that in April of 2008, the WellPoint Medical Policy & Technology Assessment Committee came to the same general conclusion outlined in the CMS decision. The commenter stated, "The WellPoint Medical Policy & Technology Assessment Committee concluded that published evidence to date is dominated by case series of patients with varying lengths of follow-up and that the few randomized sham controlled clinical trials which have been published provide conflicting results. This committee felt that the quality of many of the published studies was disappointing. With few exceptions, published studies have lacked long term follow-up to establish a durable outcome benefit, used non-standardized outcome measures and lacked adequate controls with a placebo comparator. We would agree that the published evidence to date is inadequate to establish a meaningful and durable outcome benefit for these thermal intradiscal therapies."

Response: CMS notes the comment.

Comments on patient selection criteria

Many commenters felt that TIPs, and more specifically IDET, were successful when performed with proper patient selection criteria. Some commenters felt that the IDET procedure was better suited for younger patients. Some suggested that the failures in IDET were due to the lack of adherence to strict indications for this procedure. One suggested that many physicians who performed IDET "…did not adhere to the rules mainly due to financial reasons…" referencing the workers comp peak in California 2000-2004. Another commenter stated, "I believe the problem in outcomes from intradiscal procedures stems entirely from the patient selection criteria adherance [sic] which is ignored by money seeking unethical physicians that are looking for work." This commenter was in favor of coverage for appropriately selected patients. A number of commenters made reference to the ISIS practice guidelines with specific patient selection criteria. Some commenters provided what they felt was criteria for the IDET procedure. Some of these proposed criteria are:

"…pure discogenic pain, increased with sitting, better with standing, absent neurologic symptoms and signs, clearly positive discogram in an awake patient with clear reproduction of the same pain, and adequate disc height, and the procedure should be performed technically correct with good placement of the spine cath."

"…disc height > 50%, failed other therapy, a positive discogram indicating limited disc bulge or annular tear."

"…maximum 1-2 lumbar discs, no morbid obesity, partially maintained disc height, provocation discography showing concordant pain in 1 or 2 discs."

IDET selection criteria proposed in a review article (Kloth, Fenton et al.) accepted for publication are: persistent symptoms of axial low back pain +/- leg pain and impaired function $\geq$ six months duration and non responsive to at least a six month course of conservative medical management, back pain > leg pain; history consistent with discogenic low back pain with normal lower extremity neurologic exam without marked motor deficit; one to three desiccated discs with or without small, contained herniated nucleus pulposus evidenced by T2-wieghted magnetic resonance imaging (MRI) that may exhibit a HIZ, involved disc(s) should have at least 50% remaining disc height; concordant pain provocation by low pressure (< 50psi above opening pressure) discography at the affected level(s), without pain reproduction or with discordant pain at adjacent unaffected levels at up to 50psi above opening pressure; and, posterior annular disruption such as radial and/or concentric fissure(s) to the outer annular fibers with maintenance of the anterior and lateral annulus evidenced by computed tomography (CT) discogram.

Response: *As is evidenced by the comments, there is clearly no consensus on patient selection criteria. In addition, the criteria above are different from the patient selection criteria submitted by ISIS in the initial public comments which identified that reduction in disc height should be less than 20%. The ISIS practice guideline for IDET stated that the indications for IDET differed since the operators used different criteria. In the initial public comment NASS suggested that the patient selection criteria used in the Pauza trial should be used if coverage for IDET were provided. Pauza stated that the results of his trial could not be generalized to other patient populations. The article accepted for publication (Kloth, Fenton et al.) that identifies the patient selection criteria is a review article and does not provide new clinical evidence.*

Comments on discography

Some commenters addressed the topic of discography. One commenter strongly disagreed with the CMS references used in the decision memorandum on the discussion of the utility of discography. This commenter stated, "Without a doubt discography is the standard of care [for the diagnostic workup of discogenic pain]." This commenter questioned why CMS felt it was within their purview to change the standard of care within the United States. Another commenter stated that there is not one standard of set criteria that defines a positive discogram. This commenter further stated that if a discographer desired to call a study positive they could do so simply by pushing harder and faster on the syringe, by not using a severity or concordancy requirement, or by not requiring a negative control disc. However, this commenter also stated that the use of pressure-controlled discography along with a severity or concordancy requirement, and a negative control disc used in more recent studies have demonstrated the utility of discography. There was some reference to ISIS guidelines for discography improving the utility of discography.

Response: We disagree that discography is a universally accepted standard of care among spine care providers. There is ample documentation in the literature that discography is controversial among spine care physicians. This was also evident in testimony presented at the MCAC on lumbar spine fusion for treatment of low back pain (Nov 2006). In addition the NASS publication on discography states, "Discography is a very specific tool that may help your health care provider determine if the abnormal disc is causing your pain. Due to conflicting data on the benefits of discography, the use of discography is controversial among spine care physicians. However, many health care providers do find it is helpful in identifying the source of pain." (NASS Public Education Series, Discography) In a recent editorial, Haldeman stated, "There is clearly no consensus that commonly used diagnostic tests hold any value in the decision-making process before offering a treatment for CLBP (Haldeman and Dagenais 2008)." Based on comments and discussion provided at meeting with CMS (August 4, 2008 meeting with Smith & Nephew and other interested parties), there is no standard in the physician community on the method of injection for discography. While some physicians have started to use the pressure controlled manometry devices, others rely on injection by hand. Although, the ISIS guidelines for discography are referenced there is no indication that these guidelines are the standard in the spine care community. CMS is not changing the standard; we don't believe the literature or comments support that there is a standard of care for discography across the spine care community at this time.

Comments with comparison to fusion

A number of commenters referenced fusion or back surgery as either an alternative to IDET or in a cost comparison to IDET. While one commenter declared the CMS' statement that "TIPs are proposed as an alternative to spinal fusion" as "not true" another commenter opined that IDET was "certainly equally effective, and by some reports more effective, with far lower risks and costs, than surgical alternatives such as fusion or total disc arthroplasty in the age groups that have been studied to date." Yet another commenter characterized IDET and biacuplasty "as a treatment for a subset of patients that really has debilitating axial low back pain that will not respond to any other treatment other than fusion or disc replacement…" Still another stated, "Studies of fusion versus idet compares 'apples to oranges'." A commenter described IDET as a "minimally-invasive procedure with a far more attractive safety profile than fusion and actually offers an intermediate intervention between conservative care and more invasive surgical procedures, such as fusion or artificial disc arthroplasty. IDET has the advantage of preserving the native disc structure and, thus, undergoing the procedure does not eliminate the possibility of more invasive treatments such as spinal fusion or disc arthroplasty if severe symptoms re-develop or more progressive mechanical changes ensue."

Response: While spinal fusion is not the topic of this NCA, based on comments submitted to CMS it is evident that there are differing opinions of whether TIPs are thought of as an alternative to spinal fusion and other more invasive surgical procedures. The systematic review by Andersson (Andersson, Mekhail et al. 2006) was an historical comparison of IDET and spinal fusion. CMS was clearly correct in its statement that "TIPs are proposed as an alternative to spinal fusion." However, as we also stated in the decision memorandum there is no evidence that TIPs are an alternative to more invasive surgery, particularly fusion. Djurasovic noted, "The concept that IDET is an alternative to interbody fusion surgery assumes that the treating physician has experience in selecting patients for this procedure. In the patients described in this report, fusion surgery was advised against by two different consulting surgeons. This raises the question of whether invasive treatment of any sort was indicated" (Djurasovic, Glassman et al. 2002).

Comments on procedures should not be combined under TIPS and IDET has separate procedure code

Numerous commenters felt that IDET was different from the other TIPs procedures and some supported their opinion with the fact that the AMA CPT panel gave IDET a separate procedure code. At least three commenters stated, "IDET is the only technology the AMA deemed to have sufficient evidence to warrant a separate code." One commenter stated, "I would also disagree with CMS' decision to lump all types of TIPs into one treatment. While there are similarities between technologies, since the exact mechanisms of these treatments has not been fully delineated, it would be inappropriate for CMS to suggest that they are all identical." Another commenter felt that IDET was a separate category from PIRFT and biacuplasty because the mechanism of action, location of treatment and body of supporting evidence was different.

Response: External decisions about CPT coding do not provide a basis for coverage decisions. CMS performs a thorough review and analysis of the evidence to make a reasonable and necessary decision about coverage. CMS recognizes that there are some differences among the techniques and devices employed in TIPs; however, we believe the various techniques utilized for TIPs use the same function and seek the same desired outcome (the application or creation of heat and/or disruption within the disc to relieve pain) and should be grouped under one NCA.

Several commenters requested that biacuplasty be removed from this NCA because it is currently being evaluated through ongoing RCTs. Some commenters characterized biacuplasty as promising, although not yet proven effective. One commenter stated, "…in my personal experience the utility of annuloplasty and IDET are quite limited and the results, even in carefully selected patients are disappointing. …While I agree that older technologies probably do not yield results that justify payment, this does not invalidate the anatomy or the painful condition of discogenic pain." He suggested that we should keep an open mind in reference to new treatments. One commenter suggested that leaving the coverage decision on disc biacuplasty to local contactors would facilitate the continued development of clinical evidence. Another commenter felt that the biacuplasty device should not be considered substantially similar to IDET.

Response: CMS recognizes that there are some differences among the techniques and devices employed in TIPs; however, we believe the various techniques utilized for TIPs use the same function and seek the same desired outcome (the application or creation of heat and/or disruption within the disc to relieve pain) and should be grouped under one NCA. The biacuplasty technique utilizes radiofrequency energy to produce heat from two internally cooled probes which deliver heat to a larger area within the annulus. The Baylis Trans Discal System was cleared by the FDA in January of 2007. To date there is one small published case series for this technique and major limitations of this study are identified by the author. The evidence is not adequate to determine that biacuplasty is reasonable and necessary under §1862(a)(1)(A) of the Social Security Act . If the trials that are underway provide new published evidence of benefit for the Medicare population, CMS will, upon request, reopen this NCD for reconsideration.

Two commenters felt that PDD should not be included in the NCA because they felt there are significant differences between PDD and TIPs. They stated that coblation techniques are not heat based and one stated that PDD is used to treat radicular pain associated with early stage disc degeneration by a reduction in intradiscal pressure through vaporization of nucleus pulposis.

Response: *CMS disagrees. The technology used in PDD uses radiofrequency energy combined with a conductive medium, such as saline solution, to form a plasma that supposedly dissolves disc nucleus material, at relatively low temperatures, minimizing damage to adjacent, healthy tissue. PDD utilizes both energy and heat. CMS believes this technique should remain under the scope of the TIPs NCD.*

One commenter objected to including lasers, specifically pulsed holmium lasers, with RFE and electrothermal energy devices. He felt that lasers had a different mechanism of action and cause different tissue effects and provide different clinical outcomes than RFE and electrothermal energy devices.

Response: While the proposed decision did not specifically exclude laser procedures, it was not our intention to include them. We have clarified that the scope of the NCA includes percutaneous intradiscal techniques that utilize devices that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc to promote healing. Laser procedures are intended to remove disc material and thus do not fall within this scope.

Comments on other insures will follow Medicare decision

Concern was expressed by a few commenters that other insurers would follow Medicare decision of non-coverage.

Response: Our NCD process is based on a thorough review of the evidence and how that evidence relates to the Medicare population. Our analysis is transparent and decisions are available to the public as required by law. The conclusions and coverage determinations are for our Medicare population. Although CMS is aware that other payers may choose to follow Medicare coverage policy, this is not a consideration in the NCD process. Other commercial health insurance companies have already performed their own independent review of these procedures and many came to a conclusion of non-coverage for their patient population.

C. Comments with discussion of evidence

Numerous commenters provided specific comments on the evidence and CMS' analysis of the evidence

A number of the commenters stated that CMS focused on older studies. This statement was also included in the ASIPP supplied form letters. One stated that the older studies did not employ the current patient selection criteria.

Response: CMS disagrees. Our analysis is comprehensive in including all available published studies. It is not clear what is meant by older studies, as some of the newer studies (Mauer 2008) are based on older data (abstract first presented in 2002). Additionally, another of the newer studies (Nunley 2008) contains workers compensation patients which is one of the reasons that Freeman's study has been criticized.

Some general comments on evidence suggested that "…it has never been proven that evidence based medicine provides higher quality of care than clinical decision making by the physician or practitioner." Ethical issues surrounding RCTs was also brought up even though another commenter supported the value and necessity of RCTs and stated that RCTs are even more important in interventional spine literature. This commenter believed that despite many people believing a placebo-controlled surgical study to be unethical, he believed it was "unethical not perform such a study." Another commenter felt that the conclusion of the CMS analysis "…contradicts not only the large body of peer-reviewed published literature, but also the stated recommendations of a number of physician specialty societies that represent this area of medicine." One commenter felt that the CMS proposed policy did not take into account all studies and the methodology used in each study but no specific reference was provided. A comment in the form letter stated there was substantial clinical evidence supporting the continued coverage of these procedures, particularly coverage of IDET but no specific reference was provided. One commenter felt that "current clinical literature and practice guidelines reflect a more sophisticated, stratified approach, rather than a one-size-fits-all analysis."

Response: RCTs are generally recognized as the gold standard for proving a technology improves health outcomes. This is especially true for a trial where the expected outcome is improvement in pain. CMS' review of evidence is consistent with evidence assessment by other well-respected groups such as USPSTF. Guyatt's evidence grading recommendations take into account the methodological quality of supporting evidence and the benefit vs. risk and burdens (Guyatt, Gutterman et al. 2006). For Guyatt's Grade of Recommendation to be 1C/strong, the benefits would have to clearly outweigh risk and burdens. IDET does not meet this standard. There are no trials with a control that confidently demonstrate that IDET is different than placebo. The nonrandomized trials have major sources of uncontrolled confounding and do not demonstrate a sustained response, as evidenced by the comment of an author, that patients with particular degrees of recovery at one time period are not necessarily the same patients with those degrees of recovery at a following period. The remaining five observational studies are case series, and are not designed to determine whether a treatment works or not. Four case series studies demonstrate poor outcomes.

A comment was made that the authors of most of the clinical reports on IDET concluded it was effective.

Response: Evidence assessment is a scientific investigation that focuses on a specific question and uses explicit scientific methods to identify and assess studies. The totality of the evidence is examined, as individual studies rarely provide definitive answers. The totality of the evidence does not support that IDET improves health outcomes for patients with low back pain.

A commenter stated that interventional pain management specialists have more experience in annuloplasty and therefore their recommendations are the most appropriate. He further stated that technical assessments and views mentioned in the proposed decision are incorrect in their conclusion.

Response: Interventional pain management specialists represent only a fraction of those providers who treat patients with back pain. One of the challenges that exists is that multiple groups produce recommendations in the same clinical topic area and may duplicate previous work or produce contradictory findings that remain unresolved for the clinician and patient. This does not lead to high quality patient care. However, when multiple organizations use the same methodology for recommendations and come to the same conclusion, it creates more confidence in the validity of the conclusions.

A comment was made that CMS placed little weight on patient satisfaction:

Response: To the contrary, CMS believes patient satisfaction is important and it should be measured in an unbiased manner.

A commenter stated, "…it is my understanding that evidence from foreign literature is not to be utilized in CMS reviews either in support or in deference to any treatment modality unless it is published in a peer reviewed American journal."

Response: The commenter is mistaken. CMS considers all quality publications, however, we do limit our literature searches to articles in English.

A commenter felt that CMS lumped together all single arm studies, whether prospective or retrospective, as case series. He felt that this discounted the value of prospective single arm studies versus retrospective studies This commenter stated, "that findings derived from single-arm prospective trials may be more realistic and closer to results achieved in the clinic."

Response: Case series whether prospective or retrospective do not demonstrate effectiveness in the treatment of low back pain. The strengths and limitations of case series studies are discussed in Appendix A and the analysis section. While case series can provide information about areas such as safety, they can also be subject to bias and confounding. There is no evidence to suggest that findings derived from single-arm prospective trials may be more realistic and closer to results achieved in the clinic as opposed to trials with a comparison arm.

There was a criticism of CMS for using the Rhyne 1995 article as a reference because it predated the development of TIPs technology. One commenter stated that there was an impressive imbalance in favor of IDET represented in the published literature of 35 published clinical reports with 27 authors concluding IDET was effective, three concluding it was equivocal, and five concluding it was effective

Response: CMS adheres to well accepted evidentiary standards as noted in Appendix A. When evidence is relevant to the technology under review, such as in the case of Rhyne which presents data on the non-operative results of discography, the information is not discarded based solely on date of publication. The totality of the evidence does not support that IDET improves health outcomes for patients with low back pain.

A commenter felt that CMS mischaracterized the Bogduk and Karasek study in that this study was a prospective non-randomized controlled trial.

Response: Whether the study is characterized as a prospective non-randomized control or case control does not change the analysis of the study.

A number of commenters criticized the Freeman study. One commenter felt that a major flaw of the Freeman report was that he failed to report pain severity. This commenter also felt that the absence of a placebo effect invalidates the Freeman study and criticized CMS for relying disproportionately on Freeman's results. Another commenter felt that the Freeman study had problems with the selection of patents with pain up to 20 years duration, non-standard discography and an injection of a "superdose" of antibiotics into the disc which has been shown to be toxic to disc tissue at a cellular level. One commenter felt the Freeman study should be discounted because he stated that 85% of the patients in the Freeman study had an abnormal reflex and probably had severe radiculopathy which is a wrong indication for IDET. This commenter also stated that Freeman's discography technique had high false-positives which puts the conclusion of the study in question.

Response: CMS believes that critical appraisal of evidence is important. Freeman reported SF-36 bodily pain. On close examination, there was a small treatment effect. There is no gold standard in discography or in antibiotic use (many articles do not report the dose). Other studies have included patients with abnormal ankle reflex but failed to report on how many were included. Freeman excluded patients with a structural radiculopathy.

There were a number of comments on the Pauza study. One commenter stated that Pauza clearly demonstrated an improvement in the VAS of two points which is widely accepted as clinically significant. Another commenter felt that the Pauza study supports that IDET does have benefit. Another commenter stated that the purpose of the Pauza study was not to develop selection criteria, but to determine whether IDET worked better than placebo and the commenter felt that the Pauza study showed that there was a greater improvement in IDET patients as compared to placebo in several measured categories. A commenter stated that the criticisms of the Pauza study were "…Predictable, in some cases, amount to overreach." In reference to the issue of Pauza's per-protocol analysis, this commenter stated he conducted an intention-to-treat analysis of the Pauza data on pain severity and computed a p = 0.06 for the difference between IDET and sham.

Response: CMS disagrees with the comment. The Pauza study is unconvincing as a demonstration of clinical benefit to patients with low back pain. See the discussion of the Pauza study in the analysis section of this memorandum. Additionally, it is unclear why the cited intention-to-treat analysis of IDET has not been published.

A number of the public comments suggested coverage for IDET and/or biacuplasty under coverage with evidence development (CED). This was part of the form letter supplied by ASIPP on their web site which related to IDET.

Response: CMS always considers whether the technology under review would be appropriate for coverage with evidence development. We do not believe that TIPs is appropriate for CED. The evidence does not support that TIPs is a promising technology that will provide a benefit to Medicare beneficiaries. The totality of the evidence to date does not support that TIPs improve health out comes in patients with low back pain.

Many of the public comments provided references to published articles (See Appendix D for a list). CMS reviewed all the references and all publications that were considered relevant to this topic are included in the bibliography for this document.

VIII. Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Social Security Act §1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A). This section presents the agency's evaluation of the evidence considered and conclusions reached for the assessment questions.

Our analysis focused on the following question:

Is the evidence sufficient to conclude that TIPs will improve health outcomes in the Medicare population with low back pain?

Percutaneous thermal intradiscal procedures are proposed treatments for chronic low back pain believed to emanate from the cartilaginous spinal disc. After a review of the evidence, CMS believes that the various techniques utilized for TIPs use the same function - the use of heat and/or disruption, seeking the same desired outcome - relief of pain. Some techniques have a greater representation in the published literature; however, the similarities of function and desired outcome are sufficient to support generalizing the available published evidence across all the techniques used in TIPs.

Low back pain symptoms are common, generally vague and of uncertain cause. Most patients will recover over time with supportive care though some may suffer repeated relapses throughout their lifetimes. For patients who seek help an accurate diagnostic test to determine the exact cause of low back symptoms has yet to be developed, creating a source of frustration and opportunity. These present uncertainties have created confusion for both clinicians and patients, as Haldeman stated, "Patients with chronic low back pain (CLBP) are finding it increasingly difficult to make sense of the growing list of treatment approaches promoted as solutions to this widespread problem"(Haldeman and Dagenais 2008a). Treatment approach varies based on theoretical ideas.

The theoretical mechanism of action that these procedures relieve pain by, denervating nociceptors in the posterior annulus fibrosus and stabilizing the disc by collagen modulation, remains unsubstantiated (An, Boden et al. 2003). Cohen noted, "If only nociceptive denervation were responsible for pain relief, one would expect to see rapid improvement after IDET, not the slow, progressive reduction in pain that typically follows a successful procedure" (Cohen, Shockey et al. 2002; Chou, Lew et al. 2005). Additionally, one would not expect any pain relief from repeat procedures, which are in fact performed (Cohen, Shockey et al. 2007). Another hypothesis is collagen modification which alters the biomechanics of the functional spinal segment. However, Lee did not report any change in the stability of the lumbar spine segment before and after treatment with IDET (Lee, Lutz et al. 2001). Also, Kleinstueck found the IDET catheter to be unable to generate sufficient heat to even produce the theoretical collagen changes (Kleinstueck, Diederich et al. 2001). Furthermore, Narvani studied the effect of IDET on the resolution of asymptomatic HIZ (Narvani, Tsiridis et al. 2003b). Six months post-procedure, repeat MRI revealed that there was no resolution of HIZ (Narvani, Tsiridis et al. 2003b).

The devices used in TIPs generally apply radiofrequency energy or electrothermal energy to generate heat and/or disruption within the disc space. In 2004, Deyo reported, "Most new devices are approved by demonstrating 'substantial equivalence' to a product that was marketed more than 25 years ago (before 1976). For this type of approval, a device need only do technically what it claims and be reasonably safe. A device that delivers electric current to the skin can be considered 'effective' without asking if it relieves symptoms" (Deyo 2004).

The devices for discogenic back pain in the TIPs' category utilize the transfer of energy to heat and/or disruption in the cartilaginous disc to treat back pain. All of these devices passed through the FDA under 510(K), meaning that they were found to be substantially equivalent to previous devices without the requirement of clinical trials. The TIPs devices are typically submitted as predicate devices of each other (e.g., the Oratec EndoTAC Monopolar Cautery Probe was the predicate device for the SpineCATH, the SpineCATH was the predicate device for Radionics RF Disc Catheter Electrode System, etc.). The Oratec EndoTAC Monopolar Cautery Probe was found to be substantially equivalent to devices marketed prior to 1976. The product code GEI, 21CFR§878.4400, is identified as an electrosurgical cutting and coagulation device and accessories intended to remove tissue and control bleeding by use of high-frequency electrical current, in effect describing electrocautery. Cauterization as a medical treatment has been in existence since ancient times – heating a piece of metal and applying to an open wound.

While there are claims that the devices in this category that utilize the basic principle of energy transfer are of different design, there is no evidence of significant outcome difference. The evidence does not demonstrate improved health outcomes from the use of TIPs devices in the treatment of back pain that is believed to be coming from the disc.

Uncertainty exists in the selection of appropriate patients for the various procedures to treat low back pain that is suspected to be caused by the disc. Patient symptoms alone do not accurately point to the disc as the source of pain. Identifying the pain generator in low back pain is challenging due to the anatomic complexity of the spine and poor understanding of neurophysiologic mechanisms of pain sensation (Haldeman 1999). TIPs literature maintains that for clinicians to identify patients appropriate for the procedures, positive provocative discography and either MRI and/or CT indicating IDD (or disease) should be relied on. However, the value of discography as a diagnostic tool in the identification of discogenic pain is controversial (National Board of Health, Danish Centre for Evaluation and Health Technology Assessment 2003). The benefit of discography and abnormalities in imaging studies in guiding a patient's treatment for back pain is questioned. Patients with nonspinal back pain and asymptomatic patients can have positive discography (Carragee, Tanner et al. 1999; Carragee, Chen et al. 2000). Additionally, in patients with low back pain, provocation discography can be positive in the absence of imaging structural or physiologic abnormalities (Chou, Lew et al. 2005). While imaging studies can demonstrate structural and physiologic abnormalities, there is no correlation with either the presence or severity of low back pain (Chou, Lew et al. 2005). In fact, patients can have annular tears on MRI or CT and be asymptomatic. Chou stated, "Although a bright, focal increase of T2-weighted magnetic resonance signal in the posterior annulus (the so-called high intensity zone lesion) is correlated with annular tears, it is not correlated with low back pain" (Chou et al. 2005). Slipman showed no statistical correlation between the side of the patients' concordantly painful annular tear and the side of the patients' low back pain during discography (Slipman, Patel et al. 2001). This directly questions if the annular tear, whose natural history is unknown, is the pain generator being tested during discography (Djurasovic, Glassman et al. 2002). In summary, the effect that discography has on patient outcomes (mediated through the choice of therapy) is uncertain and no specific anatomic lesion has been proven to be the source of discogenic low back pain (Rhyne, Smith et al. 1995).

TIPs are promoted as an alternative to more invasive surgery when other treatment modalities for CLBP have failed. However, there are a wide and ever-growing variety of treatment options that include activity modification, multiple pharmacological options, various types of massage, manipulations, medication assisted with manipulation, many types of exercise, multiple physical modalities, educational and psychological training, many types of injections, lifestyle therapies, and complementary and alternative therapies (Haldeman and Dagenais 2008b). It is not clear which or how many of these other treatment modalities that are less invasive (with less adverse effects) than TIPs should be offered beforehand. Furthermore, there is no evidence that TIPs are an alternative to more invasive surgery, particularly fusion. These devices are used by a variety of health care practitioners (Djurasovic, Glassman et al. 2002). Djurasovic noted, "The concept that IDET is an alternative to interbody fusion surgery assumes that the treating physician has experience in selecting patients for this procedure. In the patients described in this report, fusion surgery was advised against by two different consulting surgeons. This raises the question of whether invasive treatment of any sort was indicated" (Djurasovic, Glassman et al. 2002). For instance, Pauza himself noted that the patients in his study population had only slight to moderate disability, as judged by SF-36 and ODI (Pauza, Howell et al. 2004). These patients can hardly be judged as fusion candidates based on this assessment. Though fusion is possible after failed TIPs, the results of fusion after a failed procedure remain unknown (Djurasovic, Glassman et al. 2002). Additionally, which surgical procedure is best after failed TIPs is unknown (Djurasovic, Glassman et al. 2002). Unless patients are randomized to either fusion or TIPs, bias in patient selection can exist, as patients who do not chose surgery may have less severe conditions and may be more apt to improve (Rhyne, Smith et al.1995).

Two of three randomized placebo controlled TIPs trials (Freeman, Fraser et al. 2005; Barendse, van den Berg et al. 2001) demonstrated no benefit. The results of the third trial (Pauza, Howell et al. 2004) did not demonstrate positive results that could be translated with confidence to the Medicare population for the following reasons:

- From 4523 prospective patients, only 1.4% (64 patients) were deemed suitable for randomization.
- Inclusion/exclusion criteria effectively excluded the Medicare population.
- Inclusion criterion of a 20% reduction in disc height was difficult to interpret. There was no standard to provide uniform inclusion or exclusion.
- There was not enough information to understand how the power calculations were done.
- Type I error rate (finding a difference when in fact there is no difference) was not reported.
- Even with this highly selected group, 50% of patients had no benefit.
- Pauza stated, "The results of this trial cannot be generalized to patients who do not fit the strict inclusion criteria."
- Success criteria for pain reduction was defined post-hoc (Urrutia, Kovacs et al. 2007).
- It is unclear that the definition of success that the authors used was clinically meaningful. The clinically important change is based on an individual, but is often misused to compare the difference in mean scores between two groups, which is not a clinically important difference (MedCAC 2006).
- IDET and control groups were not equivalent at baseline, favoring IDET.
- The effect of co-interventions were not included in the analysis (Urrutia, Kovacs et al. 2007). For instance, though physical rehabilitation was monitored, compliance was not reported.
- The effect of analgesics was not mentioned. Pain can wax and wane over time so it is important that follow-up visit protocols be reported; they were not.
- Even with this small study size, 12.5% of patients were not included in the analysis.
- Numeric differences between treatment and control groups did not appear to be clinically significant, even though two measures were of statistical significance.
- VAS mean change score was reported as statistically significant and three measures of change for SF-36 bodily pain, SF-36 physical functioning, and ODI were reported as not statistically significant. Which number is to be believed (Gatchel 2004)?
- It's not clear that statistical tests were used appropriately. For example, Pauza stated, "With respect to categorical outcomes, statistically significant differences in favor of the IDET group occurred both for absolute change and for relative changes in pain scores as measured by the VAS." This was concluded from Fisher's exact test p values. Fisher's exact test is a statistical test used to determine if there are nonrandom associations between two categorical variables. It would have been more appropriate to use a test of trend (Gatchel 2004).
- For the t tests, it is not noted that the data meet criteria to use this test; however, the large standard deviation with the 6 months values may mean that the 95% tolerance interval is not achieved (Freeman 2005).
- For at least a 75% relief of pain in one patient treated by IDET, four additional patients would need to be treated who might not show this improvement. The authors do not provide the uncertainty of that estimate (Gatchel 2004).
- Stated another way, only 40% of patients treated with IDET achieved greater than 50% relief of pain, while sham treatment produced a 38% improvement in pain of greater than 20 points, with 33% reporting greater than 50% improvement and one patient reporting complete relief of pain (Gatchel 2004). Looked at this way, the treatment is difficult to distinguish from sham.

Based on these two studies, CMS can not confidently conclude that the IDET treatment is different than placebo.

Variable definitions of success cloud interpretation of the studies and make direct comparisons difficult. Work groups of experts have advocated for inclusion of standardized measures in five areas: function, symptoms, general health status, work disability and satisfaction with care. The two most important clinical outcomes in the Medicare population are standardized measures of pain and back specific function. No one CLBP measure has yet been devised that is acceptable as a primary outcome measure due to the little understood, complex nature of the disorder. Left to the choice of the investigator, the primary outcome measure(s) can significantly influence success rates. Critics of the Freeman trial disparage it because no patient met the success criteria, in contrast to Pauza, where nonspecific effects were demonstrated. Freeman admitted surprise that there was apparent lack of effectiveness in both groups, but offered as a possible explanation that patients had undergone an exercise program before the intervention, and that IDET was considered by some to be most effective when combined with an intensive exercise program. He hypothesized that it may be that the exercise program was the major component of the perceived success of IDET. Additionally, Freeman defined success a priori, whereas Pauza established his success criteria for pain reduction post hoc – after the results were known (Urrutia, Kovacs et al. 2007). The criteria between the studies are not the same, so comparison is not direct. Barendse, though a small study, suggested that the PIRFT procedure was no better than sham. The follow-up to Barendse was Ercelen where he tried two different techniques to see if this made a difference: it did not.

Two nonrandomized trials (Bogduk, Karesek et al. 2002; Kapural, Hayek et al. 2005) showed positive results for IDET compared with rehabilitation and PIRFT, but these outcomes need to be examined more closely. Patients in the Bogduk study had to have the height of the affected disc preserved to within 80% of expected normal height (as in Pauza). There is no standard way to measure this. Neither trial had blinding and both had major sources of uncontrolled confounding. In the trial comparing IDET to rehabilitation, the control group wanted IDET but did not get it due to insurance problems and were pursuing litigation to have the procedure done (Urrutia, Kovacs et al. 2007). All patients in the control group failed to follow-up at that practice, so expectations would be for a poor outcome, particularly considering the strong influence of expectation response in pain treatments; hence, though the control group was contemporaneous, it was misleading to use this as a basis for genuine comparison. Other potential confounders were not measured (Urrutia, Kovacs et al. 2007). For outcomes assessment in low back pain, measures in five areas are recommended to reflect the complexity of the disorder and to examine outcomes on the basis of an individual success. It is particularly difficult to interpret what the single value of a change in median VAS means to an individual, particularly in light of the variability of VAS scores. As Bogduk noted, "…patients with particular degrees of recovery at one time period are not necessarily the same patients with those degrees of recovery at a following period." In the small trial (Kapural, Hayek et al. 2005) comparing IDET to PIRFT, patients were matched on various characteristics but uncontrolled confounding was still likely.

The results of these trials aren't generalizable to the Medicare population. The mean age of the patients in the studies was between 40 and 50 years. Only one study listed co-morbidities such as diabetes. Most studies excluded patients who had a medical condition that would interfere with follow-up, yet did not clearly define this exclusion.

The remaining clinical studies on TIPs are case series. By their design they do not test the hypothesis of treatment efficacy. A few treatments have been accepted on the basis of case series, only when the treatment effect is very large and generally obvious – but generally not for a low back pain treatment (Carey and Boden 2003). Case series are particularly problematic in the evaluation of low back pain treatments for the following reasons: the natural history of the syndrome of discogenic pain is unknown, so we can not know when, if and how much a patient will improve without treatment; there is regression to the mean in the study of pain, meaning pain has a tendency to wax and wane over time (and patients typically enter studies at the height of their pain, so they probably will regress to the mean during the study); the placebo effect, also known as expectation response, plays an important role in the treatment of pain. Without a valid comparison group we cannot know the true merit of a treatment. Therefore, in case series biases and confounding are to be expected so less weight is given to these studies. Overall, the case series results have been mixed, with the best results by the IDET inventors Saal and Saal (58 patients) reporting a three point decrease in the VAS over an average of 28 months, and the worst reported results by Webster (142 patients treated with IDET) with 22.5% having subsequent surgery during follow-up and unchanged narcotic use over an average of 22 months. There was only one published case series for the biacuplasty technology with only 15 patients and a six month follow-up. This study was unremarkable. There were eight published case series for PDD with limited reporting. One of the authors questioned for what population this procedure was appropriate.

What information can be obtained by case series? Carey and Boden suggested that case series can provide some important information in the area of case definition, trend analyses regarding outcomes, and hints as to causation. High quality case series study design is required to be able to obtain useful information for patient management. Carey and Boden suggested eight characteristics of good case series reports: clearly defined question; well-described study population; well-described intervention; use of validated outcome measures; appropriate statistical analyses; well-described results; discussion/conclusions supported by data; funding source acknowledged. The TIPS case series reports meet few of these criteria. There are other characteristics of these studies that lessen one's confidence in their reporting. For instance, Maurer 2008 with 56 patients (patients enrolled between April 1998 and October 2002) resembles an abstract from NASS 16th Annual Meeting (Maurer and Squillante 2002) where 78 patients are reported somewhat differently. Some articles referred to a prospectively collected database (Derby, Lee et al. 2004), or a "nationwide registry" initiated in 1998 by the sponsor to study outcomes through a two year post procedure follow-up (Thompson, Eckel 2002), which caused one to wonder who was included in the published articles and why. There appears to be a lack of independence among some studies, meaning that the same patients may be reported in more than one study, without this being clearly disclosed (Davis, Delamarter et al. 2004). For instance, in 2001, Welch, Gerszten, and McGrath reported on 23 patients that are very similar to the 27 patients in the 2002 article by Gerszten, Welch, McGrath, and Willis. The studies could provide evidence of safety, but not all included studies reported on complications, and those that did used definitions provided by the authors as opposed to a standard, so we don't know how much safety information can be gleaned from these studies. Unfortunately, despite the numerous issues that influence the quality and value of many of these case series, they were published in peer reviewed journals that people rely on for direction in the care of patients.

Adverse events were poorly characterized, and not reported at all in some studies. Using various definitions of adverse events made interpretation and comparison difficult. Some patients required subsequent surgery (as high as 22.5% in one case series) during follow-up, and it was not clear if this was due to treatment failure or adverse events. The case reports of cauda equina syndrome, vertebral osteonecrosis, and giant herniated disc were concerning. Despite the availability and reported high volumes of the procedure in the United States since the late 1990s, there are no long term safety data. If adverse events aren't systematically collected and the literature fails to report adverse events in a standardized fashion, or simply fails to report adverse events, you can't conclude that a device is safe.

Andersson's systematic review (Andersson, Mekhail et al. 2006) and Appleby's meta-analysis (Appleby, Andersson et al. 2006) used poor quality studies to arrive at erroneous conclusions. Incompletely reported case series were included, and the systematic review (Andersson, Mekhail et al. 2006) mistakenly included the same patient population reported in several articles. As discussed above, case series studies do not provide adequate evidence of health benefits from TIPs. The systematic review last author (and correspondence author) was a paid consultant (Andersson, Mekhail et al. 2006), and the first author (and correspondence author) of the meta-analysis was a sponsor employee (Appleby, Andersson et al. 2006).

Financial disclosure is not mentioned in some of the published articles, or is difficult to readily interpret (for instance conflict of interest reported as a category that is a number). Nondisclosure suggests that there may be something to hide, whether there is or not (Anderson, Boden et al. 2002). Importantly for patients who receive advice on treatments, the editors of *Spine*, stated, "In other words, financial conflict often skews the results of clinical and basic research toward favoring the drug or device in question." Well-designed, high-quality clinical trials must address both the complexities and biases, real and/or perceived, that exist. This includes the potential biases from funding sources. Shah's retrospective review of articles published in the journal *Spine* identified, "industry supported studies had a greater frequency of positive results than studies with any other funding sources"(Shah, Albert et al. 2005). Weinstein et al. noted, "An important concern is that many conflicts are not currently disclosed" (Anderson, Boden et al. 2002). Nondisclosure by investigators continues to occur (Henschke 2008; DeAngelis 2008). The public's current concern is reflected by the Institute of Medicine's convening a committee on conflict of interest in medical research, education and practice to develop a consensus report.

Conclusion

Identifying the pain generator in low back pain is challenging due to the anatomic complexity of the spine and poor understanding of neurophysiologic mechanisms of pain sensation (Haldeman 1999). There is no convincing evidence that current diagnostic techniques are helpful in patient management. The growing incidence of nonspecific low back pain in the Medicare population (Weiner, Kim et al 2006) in the face of a lack of self-assessed improvement in the patient population with spine problems (Martin, Deyo et al. 2008), despite the rapid progression and adoption of new technologies to the spine market, causes great concern. When examining treatments for chronic low back pain, clinical trials with a placebo comparator and consensus recommended standardized measures that reflect the complexity of the disorder are most helpful for evidence of clinically meaningful benefit.

For TIPs, the mechanisms of action remain theoretical. A thorough review of the empirical evidence on TIPs is adequate to determine that there is no convincing evidence to demonstrate a benefit to health outcomes from these procedures.

The evidence for IDET included two RCTs, one case control study, one prospective matched control study, twenty-three case series, two systematic reviews and one meta-analysis. The totality of this evidence is sufficient to determine that IDET does not improve health outcomes for patients with low back pain.

The evidence for PIRFT came from one RCT and one prospective randomized dosing trial. The evidence for PIRFT is sufficient to determine that PIRFT does not improve health outcomes for patients with low back pain.

The only published peer reviewed evidence to date for biacuplasty is limited to one small case series. This evidence is insufficient to show that biacuplasty improves health outcomes for patients with low back pain.

The evidence for PDD is limited to eight case series. These case series do not provide convincing evidence that PDD improves health outcomes for patients with low back pain.

The quality of many of the studies is disappointing and the lack of sufficient documentation of adverse events and long term outcomes is disconcerting. Therefore, CMS has determined that TIPs are not reasonable and necessary.

IX. Decision

The CMS has concluded that the evidence does not demonstrate that thermal intradiscal procedures improve health outcomes. Thus, CMS has determined that TIPS are not reasonable and necessary for the treatment of low back pain. Therefore, CMS is issuing a national noncoverage determination for TIPs under §1862(a)(1)(A) of the Social Security Act.

Appendices

Appendix A

General Methodological Principles of Study Design

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine whether: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

CMS divides the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention’s risks and benefits.

The issues presented here represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has unique methodological aspects.

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias)
- Co-interventions or provision of care apart from the intervention under evaluation (confounding)
- Differential assessment of outcome (detection bias)

- Occurrence and reporting of patients who do not complete the study (attrition bias)

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens, and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease, and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing, and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage decisions for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation), and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations because one of the goals of our determination process is to assess health outcomes. We are interested in the results of changed patient management not just altered management. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. For most determinations, CMS evaluates whether reported benefits translate into improved health outcomes. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

Appendix B
Case Series Table and Summary Thermal Intradiscal Procedures

Author/Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow-up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Saal and Saal 2002	IDET prospective	62(4) Mean age 40.5 years (range 20-59 years)	28 months(24-35)	VAS score SF-36(PF) SF-36(BP)	6.8 (+/- 1.9)3.4 (+/- 2.0) 40.5 (+/- 25)71.8 (+/- 23) 29.8 (+/- 16.0)51.7 (+/- - 22.6)

Author/Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow-up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Derby Eek Chen O'Neill Ryan 2000	IDET prospective	32 Mean age 42	12 months	VAS score (change) Roland-Morris (change)	-1.84, SD 2.38 -4.03, SD 4.82
Gerszten Welch McGrath Willis 2002	IDET prospective	27 Mean age 41	12 months	ODI SF-36(PF) SF-36(BP)	34 30 32 47 27 38
Welch Gerszten McGrath 2001	IDET prospective	23(16) Mean age 39	3 months	ODI SF-36(PF) SF-36(BP)	34 26 31 47 5 25
Spruit and Jacobs 2002	IDET prospective	20(1) Mean age 37.6 years(range 26-56)	6 months	VAS ODI	6.5 (SD 1.5, range 42-96)5.1(SD 2.7, range 2-100) 43.1(SD 7.3, range 26-52)36.7(SD 21.1, range 0-64)
Nunley Jawahar Brandao Wilkinson 2008	IDET Prospective/ workers comp	53 Mean age 42(range 20-61)	56 months (range 29 to 72 months)	VAS ODI	63.8 (range 0 - 100) 19.4 24.8 (range 0 - 41) 5.2
Park Moon Park Kim Choi Lee 2005	IDET prospective	25 Average age 32 years (range 18-49)	12 months	VAS	7.3 4.9 32% (8 patients) had more pain 5 patients had fusion
Singh 2000	IDET Prospective	23(2) Mean age 44.6 range 24-60	6 months	Pain relief Narcotic use	67% of patients had $\geq$ 50% pain relief Decreased by 29% (not statistically significant)

Author/Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow-up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Freedman Cohen Kuklo Lehman Larkin Guiliana 2003	IDET Retrospective/ active duty soldiers	41(10)	29.7 months(24-46)	VAS At least 50% reduction in pain surgery	52% had $\geq$ 2.0 improvement 5/31 (16%) 7/31 (23%) had surgery During follow-up
Kapural, Mekhail, Korunda, Basali 2004	IDET Prospective/ One or two level IDET versus 3 or greater level IDET	34 Average age 45.3 years (multilevel) 41.6 years (single level)	12 months	VAS 1 or 2 level IDET $\geq$3 level IDET Pain disability index	7.7 ± 22.5 ± 2.4 7.4 ± 1.84.9 ± 2.9 Improved in both groups
Mekhail, Kapural 2004	IDET prospective	34(2) Age range 25 to 62	12 months	VAS workers Comp (n= 10) Other(n= 22) Pain disability index	7.4 ± 1.54.3 ± 2.5 8.0 ± 1.61.8 ± 1.8 Improved
Cohen Larkin Abdi Chang Stojanovic 2003	IDET Retrospective	79 Mean age 37 (15-60)	6 months	VAS (SD) Positive Outcome Negative Outcome	38 patients 5.9 (1.8) 2.1 (1.3) 41 patients 6.2 (1.9) 5.1 (1.8) 8/79 (10%) complication rate
Lutz Lutz Cooke 2003	IDET prospective	33 Mean age 40 (range 20-56)	15 months	VAS Low back Lower Extremity Roland-Morris	7.5 3.9 5.7 2.0 13.9 6.6

Author/Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow-up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
					2 patients had repeat IDET 5 patients had other related surgeries
Lee Cooper Lutz Lutz Hong 2003	IDET prospective	62(11) Average age 41.4 years (range 18-60)	34 months (range 6-47)	Visual numeric pain scale Low back Lower Extremity Roland-Morris	7.9(± 1.3)4.7(± 3.0) 5.0(± 3.6)2.7(± 3.2) 15.4 (± 5.3)8.8 (± 7.5) 2 patients had repeat IDET 5 patients had other related surgeries
Maurer Block Squillante 2008	IDET Prospective	56 Mean age 39.5(± 11.6)	20.5 months (range 12-24)	VAS	6.1 (± 1.8) 2.4 (± 2.6) 2 patients had surgery during follow-up
Davis Delamarter Sra Goldstein 2004	IDET Retrospective	60(16) Average age 40(25-64)	12 months	Employed Surgery Pain	16 pre IDET 11 post IDET 6/44 (14%) had surgery during follow-up 97% continued to have back pain
Webster Verma Pransky 2004	IDET Retrospective/ workers compensation	142 Mean age 37.4 (21-57)	22 months (10-34 months)	Narcotic use Surgery Work status	Unchanged 32/142 (22.5%) had surgery during follow-up 58% not working at 24 months
Endres Fiedler	IDET Retrospective	54 Mean age 40	12-108 weeks post IDET	Return to work	66% of patients(35)

Author/Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow-up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Larson 2002		(17-63)		VAS	≥ 2 change in 31 patients (65%)
Derby Eek Lee Seo Kim 2004	IDET Retrospective/ IDET comparison to intradiscal injection	74 IDET 35 intradiscal injection Mean age 42 (17-62)	IDET 15.5 months Intradiscal injection 7.7 months (overall range 6-18 months)	VAS change IDET Intradiscal injections	 1.3 2.2 47.8% of IDET patients reported that they felt better 65.6% of injection patients felt better
Derby Lee Seo Kazala Kim Kim 2004	IDET Retrospective/ Included patients with referred leg pain from disc (no nerve compression)	129(30) Mean age 43 (17-62)	18 months average	VAS 5 point scale	Back pain: 3.37 +/-0.82 2.59 +/- 1.08 Leg pain: 2.36 +/-1.25 1.79 +/- 1.35 30/129 underwent subsequent back surgery
Cohen Shockey Carragee 2007	IDET Retrospective/ Repeat IDET	9 Mean age 46 Age range 32-56	6 months	VAS	Single level:7.2 (SD1.1) 4.4 (SD 2.4) Two level: 7.0 (SD 1.4) 4.8 (SD 2.8)
Bryce Nelson Glurich Berg 2005	IDET unspecified	51(21) Male median age 40.5 (range 25-73) Female median 37.3(range 21 - 55)	18 months	VAS Current day Last week Roland Morris	 -1.5 (SD 2.9) for n= 23 -2.4 (SD 3.2) for n= 23 Change of -26.7 (SD 36.0) for n=30
Ergun Sekerci Bulut et al. 2008	IDET	39 Mean age 41 Age range 20-62	18 months	Turkish ODI Baseline 6 months 12 months 18 months	 46 (SD 12) 25 (11) 23 (SD11) 22 (SD 10)

Author/Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow-up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
		Mean duration of back pain 32 months (range 14 -72).			
Kapural Ng Dalton Mascha Kapural de La Garza Mekhail 2008	Biacuplasty prospective	15(2) Age range 22-55	6 months	VAS ODI SF-36 PF SF-36 BP	7 (95% CI 6,8) 3 (95% CI 2,5) 23.3 (SD 7.0) 17.1 (SD 8.1) 51 (SD 18) 70 (SD 16) 38 (SD 15) 54 (SD 23)
Sharps Isaac 2002	Nucleoplasty prospective	49 (36) Mean age 38 Range 30-61 years	12 months	VAS	7.9 (+/- 1.3) 4.3 (+/- 2.8)
Singh Piryani Liao Nieschulz 2002	Nucleoplasty	67 (26) Mean age 44 Range 15-62	12 months	VAS	6.8 (+/- 1.1) 4.1 (+/- 2.5)
Singh Piryani Liao 2003	Nucleoplasty Prospective (Chronic back pain with or without leg pain)	80(11) Mean 44.8 years Range 15-62 years	12 months	VAS	6.83 4.5
Singh Piryani Liao 2004	Nucleoplasty prospective	47(10) Mean 44years Range 15-62 years	12 months	VAS	6.7 (+/- 1.14) 4.4 (+/- 2.34)
Yakovlev Tamimi Liang Eristavi 2007	Nucleoplasty retrospective	22 Mean age 39 Range 22-51 years	12 months	VAS Reduction in opioids intake	7.6 (SD 1.2) 3.3 (SD 3.6) 72.7% of patients
Masala Massari Fabiano	Nuecleoplasty	72(2) Mean age 48 Range 32-64	12 months	VAS	8.2 4.1

Author/Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow-up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Ursone Fiori Pastore Simonetti 2007		years			
Mirzai Tekin Yaman Bursali 2007	Nucleoplasty Prospective One and two level	52 (3) Mean age 44.8	10 to 15 months	VAS ODI Analgesic intake (not defined)	7.5 (+/- 1.3) 2.1 (+/- 1.6) 42.2 (+/-5.5) 20.5 (+/- 8.9) 94% of patients stopped or reduced analgesics
Cohen Williams Kurihara Griffith Larkin 2005	Nucleoplasty with or without IDET	16 Mean age 36 7 Nucleoplasty only	Average 9 months	VAS	6.7 5.6

Case Series Summaries

IDET

Saal JS, Saal JA. Management of Chronic Discogenic Low Back Pain with a Thermal Intradiscal Catheter. Spine 2000;25(3);382-388.
Saal JA, Saal JS. Intradiscal Electrothermal Treatment for chronic discogenic Low Back Pain. A prospective outcome study with minimum 1-year follow-up. Spine 2000;25(20);2622-2627.
Saal JA, Saal JS. Intradiscal Electrothermal treatment for chronic discogenic low back pain. Prospective outcome study with a minimum 2-year follow -up. Spine 2002;27(9);966-974.

The above three articles related to the same study group by the inventors of IDET, Saal and Saal. A total of 1116 patients with chronic low back pain (defined as back pain for greater than three months) were referred to by the authors from November 1997 to October 1998. Sixty-two of these patients failed to improve with a comprehensive nonoperative treatment program (no details given). These patients were evaluated by discography and selected IDET rather than fusion or chronic pain management.

Inclusion criteria:

- Unremitting, persistent low back pain of at least 6 months continuous duration.
- Lack of satisfactory improvement with a comprehensively applied nonoperative care program which included back education activity modification, progressive intensive exercise, at least one fluoroscopically guided epidural corticosteroid injection, a trial of manual physical therapy, and oral anti-inflammatory medication.
- Normal neurologic examination.
- Negative straight leg raise.
- An MRI with no neural compressive.
- Positive discography defined as concordant pain at low pressure ($\leq$ 1.25 mL volume) at one or more levels (maximum3 levels) with adjacent control levels not demonstrating pain.

Exclusion criteria:

- Inflammatory arthritides.
- Nonspinal conditions that could mimic lumbar pain.
- Medical or metabolic disorder that would preclude appropriate follow-up and participation.
- Patients who have had prior surgery at the symptomatic level.

Each patient was offered fusion by an independent spine surgeon but all 58 patients chose IDET. Informed consent was signed. The thermal catheter protocol included only local anesthesia with medication intra-procedure for pain, heating for 13 minutes to a catheter temperature of 90 degrees and then maintaining at that temperature for four minutes. After the procedure, patients received 2-20 mg of cefazolin but no other medications intradiscally. Post-procedure care included instruction of gradual progression of physical of exercise until the fifth or sixth month when skiing, running, and tennis were allowed. Some patients had formal physical therapy. The VAS, sitting tolerance, and the SF-36 were collected at six months, 12 months, and a minimum of 24 months follow-up. Forms were completed in private. Described data methods were determining the change in response. Pretreatment VAS scores for 20 months were analyzed by repeated measures of variance to determine if pain scores changed before the procedure (the results were reported as a graphical group mean, individual variation in values not reported).

Limited demographics

Age(mean)	40.5 years (range 20-59)
Insurance	38 private pay 20 workers compensation
Duration of preoperative symptoms (mean)	60.7 months (range 10 months to 17 years)
Duration of preoperative symptoms (median)	48 months

Duration of follow-up time in the study was a mean of 28 months with a range of 24 to 35 months. No complications were reported as defined by no nerve injuries, no infections, and no neurologic deficits. One patient did have a fusion.

Saal and Saal results

Time	SF-36 Physical function	Sitting tolerance (min)	SF-36 bodily pain	VAS (0-10)
Pretreatment	40.48 ± 25.02	32.64 ± 47.52	29.79 ± 15.97	6.57 ± 1.85
Posttreatment				
6 mo	55.60 ± 22.96	47.52 ± 37.68	42.28 ± 14.97	3.71 ± 1.95
12 mo	60.34 ± 22.20	48.28 ± 37.53	46.93 ± 19.17	3.52 ± 2.30
≥ 24mo	71.81 ± 22.88	85.34 ± 61.19	51.66 ± 22.58	3.41 ± 1.96

The authors stated, "At 24 months posttreatment 72% of the patients experienced at least 2-point improvement in pain based on the VAS scale and 50% of the patients exhibited at least a 4-point reduction in pain. Similarly, 78% of the patients showed at least a 7-point improvement in the bodily pain scale of the SF-36 and 59% showed at least a 14-point improvement." Ninety-seven percent of the private pay patients and 83% of the workers compensation patients returned to work. The authors concluded, "a cohort of patients suffering from chronic discogenic low back pain who had previously failed to improve with comprehensive nonoperative care demonstrated a statistically significant improvement in VAS, sitting tolerance time, and SF-36 scores at 2 years after IDET."

Kapural L, Mekhail N, Korunda Z, Basali A. Intradiscal Thermal annuloplasty for the treatment of lumbar discogenic Pain in Patients with Multilevel degenerative Disc Disease. Anesth. Analg 2004;99:472-476.
Mekhail N, Kapural L. Intradiscal Thermal Annuloplasty for Discogenic Pain: an Outcome Study. Pain Practice 2004;4(2):84-90.

These two studies had many similarities and it would seem that half of the patients from the Mekhail study were included in the Kapural study. The objective of the Mekhail study was to examine the hypothesis that additional inclusion criteria for patient selection, such as disc height, absence of degenerative disc disease (DDD) in untreated discs (one or two level DDD allowable), absence of herniated nucleus pulposus or lumbar canal stenosis, may improve the outcome of treatment. The Kapural study was designed to examine the value of IDTA (IDET) in patients with multilevel degenerative disc disease, however they were compared to 17 patients with only one or two level DDD that did not seem to be considered part of this enrollment group though it was not stated where they came from. It would seem that these patients were drawn upon from the 34 patients in the Mekhail study. In Kapural, 17 patients aged 24-66 years with multilevel degenerative disc disease were enrolled and patient demographics and clinical characteristics were limited to age, sex, weight, smoking and manual labor. Mekhail enrolled 34 patients aged 25 to 62 with type of insurance coverage noted but no other demographics or patient characteristics listed. It was not reported how or where the patients were recruited from.

Kapural enrollment criteria (17 patients with multilevel DDD)	**Mekhail enrollment criteria** (34 patients)
chronic low back pain for more than 6 months unresponsive to nonoperative care	chronic low back pain for more than 6 months unresponsive to nonoperative care
no evidence of compressive radiculopathy	no evidence of compressive radiculopathy

no previous surgery at the symptomatic disk levels	no previous surgery at the symptomatic disc levels
disk height maintained at least at 50% of normal adjacent discs	disc height maintained at least at 50%
no symptoms or signs of lumbar canal stenosis	no symptoms or signs of lumbar canal stenosis
	positive provocative discography
	single level disease or two levels without additional degenerative changes
	no evidence of internal nucleus pulposus herniation on MRI
	no psychological issues

In Mekhail, 34 patients had IDTA under local anesthesia with mild sedation. The coil was heated to 85 to 90 degrees and maintained for four minutes. There was difficulty in placing the catheter in one patient and this patient was lost to follow-up. The same physician conducted all of the diagnostic discographies as well as the treatment. Patients were followed over a period of 12 months by filling out the pain disability questionnaire (not indicated if this instrument is validated) before IDTA, at two weeks, two, three, six, nine, and 12 months (this questionnaire is reported graphically as ADL which is confusing). Wilcoxon signed rank tests were used to show overall differences in scores between months and Wilcoxon rank sum tests were used to compare scores between groups. The data was presented in graphical form but was difficult to interpret. A table gave the group means for 22 patients as the VAS being 8 before IDTA and 1.73 after IDTA without giving standard deviation or other outcomes. ADLs (believed to be the pain disability questionnaire) reported graphically as point estimates appeared to be improving over time. No co-interventions, such as physical therapy or analgesia, were reported. The authors reported that 82% of non-workers comp returned to work whereas only 40% of workers comp returned to work. No adverse events were reported. The authors concluded, "We believe that IDTA is an effective, minimally invasive treatment for discogenic pain in properly selected patients."

In Kapural, provocative discography was performed without details of pressure/volume being reported. The procedure was done under local, heating the coil to 90 degrees and maintaining for four minutes. No details of any other treatments, such as intradiscal injections, were given or post-op care. Patients had multiple levels of DDD. Sixteen patients had more than two positive discs. The decision on which discs to treat was based on the intensity of pain on provocative discography. For outcome measurement, the authors stated that a pain disability index (PDI) (seven activities of daily living) questionnaire was collected a number of times before IDTA and at one year after IDAT, in addition to VAS, but the visit protocol was unclear. The authors did not say that the PDI questionnaire was validated and there was some confusion if the reported PDI also contained the VAS score, so the VAS may be reported twice. Data collection and analysis were completed by a third party. Statistical analysis was described as a mixed model analysis that looks at all time points simultaneously. To assess group differences the Kruskal-Wallis test was used but it was not stated if data prerequisites were met. Study patients were matched on spine levels on which they had IDET, age, sex, history of manual labor, smoking, and weight with 17 non-study patients (but it's not clear where this patient data was derived from). The data was not presented in a table format creating difficulty in result interpretation. It was not reported how many patients were represented in the results. Adverse events were not reported. The 1-2 level DDD patient group had a mean of 2.5 +/-2.4 VAS at 12 mo (starting score mean 7.4 +/-1.8) the other group had a mean VAS score of 4.9+/-2.9 at 12 months (starting mean score 7.7 +/-2). Graphically, the PDI in both groups started out at 55 to 60 and at 12 months the 1 or 2 level group was about 20 with the multilevel about 40. The authors concluded that IDTA was an effective treatment of discogenic pain and that the number of discs affected by degeneration was an important determinant of the procedure outcome.

Lee M, Cooper Lutz G, Lutz, Hong H. Intradiscal Electrothermal Therapy (IDET) for treatment of chronic Lumbar Discogenic Pain: a Minimum 2-Year Clinical Outcome Study. Pain Physician 2003;6:443-448.
Lutz C, Lutz G, Cooke. Treatment of Chronic Lumbar Diskogenic Pain with Intradiskcal Electrothermal Therapy: a Prospective Outcome Study. Achieves of Physical Medicine and Rehabilitation 2003;84:23-28.

These two studies were very similar except for patient numbers (Lutz-33; Lee- 51) and observation time (Lutz: mean follow-up of 15 months; Lee: average follow-up 34 months). Lee reported that the patients underwent the procedure between 1999 and 2001 and that the patients were recruited from an academic-affiliated private physiatric practice; Lutz does not report when the data was collected ("Patients were recruited from the academic -affiliated private physiatric practice of one of the authors (GEL)"). Some of the similarities were: same corresponding author and institution (Gregory E. Lutz, Hospital for Special Surgery); same year of publication; same patient symptom duration of 46 months; same outcome measures (VAS for back and leg, Roland-Morris Disability Questionnaire, and the North American Spine Society Patient Satisfaction Index), except Lee referred to the visual numeric pain scale (VNS) for low back (LB) and lower extremity (LE) pain, whereas Lutz referred to visual analog scale (VAS) for the back and lower extremity; outcomes listed by single and multiple levels; IDET procedure description; post-procedure rehab description; additionally, some sentences are the same or have very similar meaning.

Demographics and clinical characteristics that were included in the studies

	Lutz	**Lee**
Age mean (years)	40 (range 20-56	41 (range 18-60
Duration of symptoms	46 months (range 6-120)	46 months (range 6-160)
workers Comp	45%	20 patients
Gender	16 women, 17 men	22 females, 29 males

Lutz	Lee
Inclusion	
6 mo. Low back pain moderate to severe in intensity	6 mo. Low back pain moderate to severe
Ineffectiveness of appropriate nonoperative care	Failure of conservative care
Positive discogram	Positive discogram
Less than 5mm disc protrusion on CT	Sitting > standing pain Less than 5mm disc protrusion on CT Normal neurologic exam No neural compressive lesion
Exclusion	
50% disc height vs. normal disc	50% disc height vs. normal disc
Sagittal canal < 10 mm	Sagittal canal < 10 mm
Spondylolisthesis Spondylolysis	Spondylolisthesis > grade 1

Lutz	Lee
Previous spinal surgery	Previous spinal surgery not excluded
Segmental instability	Segmental instability
Systemic infection	

In both studies, not all patients tolerated the standard high-heating protocol (gradual increase to 90 degrees and then held at that temperature, total heating time 16.5 minutes). An alternate protocol was described in Lutz but not in Lee. Lutz described difficulty with catheter placement. For both studies, paired t tests were used to compare pre and post VAS and Roland Disability scores with Lee reporting the tests were two-tailed. Suitability of data for chosen statistical tests was not reported. ANOVA was used to compare subgroups.

Results:
Lee, Overall Results (mean ± SD) *

	Pre-IDET	Post-IDET	change	p-value
VNS, low back (n= 51)	7.9 ± 1.3	4.7 ± 3.0	-3.2 ± 3.0	< 0.001

	Pre-IDET	Post-IDET	change	p-value
VNS, lower extremity (n= 51)	5.0 ± 3.6	2.7 ± 3.2	-2.3 ± 4.1	< 0.001
RM (n = 50)	15.4 ± 5.3	8.8 ± 7.5	-6.6 ± 7.5	< 0.001

* The visit at which these scores come from was not reported.

The authors reported that for their subgroup analysis there was no statistical significance between single versus multilevel outcomes or by insurance subgroups.

Lutz, Overall Results (mean) # +

	Pre-IDET	Post-IDET	change	p-value
VNS, low back (n= NR)	7.5	3.9	3.9	< 0.001
VNS, lower extremity (n= NR)	5.7	2.0	3.7	< 0.001
RM (n= NR)	13.9	6.6	7.3	< 0.001

	Pre-IDET	Post-IDET	change	p-value

#The visit at which these scores come from was not reported.
+ standard deviation was not reported
NR = not reported

Lutz reported that in 15% of the 33 patients, a steroid injection was necessary because of pain, but the authors did not report this as a failure. One patient had surgery. The authors reported, "There were no complications of dural puncture or tear, infection, or nerve injury," but did not qualify the time frame or mention other types of adverse events. Analgesic use was not mentioned.

Lee reported that there were no peri- or post-procedural complications of dural puncture, infection or nerve injury, but 14% (7) of patients underwent additional therapeutic procedures during the follow-up period. Lee identified nine post-IDET procedures performed which included two fusions. Oral analgesic (not defined) use decreased in 30 of 44 patients (7 of 51 patients were not accounted for).

Lutz concluded, "This study supports the use of IDET as a safe, minimally invasive outpatient procedure for treating patients with symptomatic lumbar disk disease whose pain was not relieved with aggressive nonoperative care. Prospective, randomized, controlled studies are needed to validate IDET more definitively as an effective treatment for these patients." Lee concluded, "IDET appears to be an effective treatment for chronic lumbar discogenic pain in a well-selected group of patients with favorable long-term outcome," and, "Clearly further research is needed in randomized placebo-controlled studies to more definitively evaluate clinical efficacy of IDET in treating chronic lumbar discogenic pain and elucidate mechanism of action of intradiscal electrothermal treatment."

Nunley P, Jawahar A, Brandao S, Wilkinson K. Intradiscal Electrothermal Therapy (IDET) for Low Back pain in Worker's Compensation Patients. Can it Provide a Potential Answer? Long-term Results. Journal of Spinal Disorders Technology 2008. 21:11-18.

The objective of this case series was to evaluate improvement in pain and disability in 53 consecutive workers compensation patients with low back pain. Patients were seen at a private clinic and treated by a single provider from 1999 to 2003. The authors stated, "Although there are no set norms in the literature about the eligibility of patients for the IDET procedure, we have learned from personal experience that the results of the procedure are not always encouraging for all patients with LBP. Hence we follow our own institutional policy of offering the IDET procedure to only the patients who satisfy certain clinical and radiographic criteria." There was no explicit statement of either study exclusion or inclusion for this group of patients. The IDET technique was mentioned but differs from descriptions in the literature in that the coil temperature was 90 to 95 degrees and was maintained at the level for at least five minutes. They commented, "There are several pathways for the catheter placement that have been recommended in the literature by previous investigators but the choice varies according to individual physician's philosophy." Follow-up protocol was unclear except that they were seen 12-months post-procedure. Outcomes were assessed by VAS and ODI using paired t tests to before and after scores. It was not noted that the data met criteria to use these statistical tests.

Demographics and clinical characteristics:

Age, mean (range) years	42 (20-61)
BMI, mean (range)	28.4 (20.1- 44.4)
Ethnicity	52.8% white, 30.2% African-American, 17% Hispanic
VAS initial score	64 (0 - 100)
ODI initial score	25 (0 - 41)

Results:

	Mean	SD	reported t	p
VAS initial – VAS post-IDET*	44	± 40	7.989	0.000
ODI initial – ODI post-IDET*	20	± 14	10.318	0.000

*It was not clear when these scores were measured.

Follow-up time ranged from 29 to 72 months.

Adverse events were not discussed. Twenty-seven patients were consuming narcotic analgesics on a regular basis "on presentation" and at a median of 12 months the number was reduced to seven patients (no further details were given, such as their definition of regular basis). The authors concluded, "IDET can be a useful, safe, and cost-effective option in the management of carefully selected workers compensation claimants with chronic LBP of discogenic etiology."

Park SY, Moon SH, Park MS, Kim HS, Choi YJ, Lee HM. Intradiscal Electrothermal Treatment for Chronic Lower Back Pain Patients with Internal Disc Disruption. Yonsei Medical Journal 2005;46(4):539-545.

The purpose of this study was to evaluate the efficacy of IDET for patients with chronic lower back pain. Twenty-five patients received IDET between 2001 and 2003. The patients had MRI to diagnose internal disc disruption and provocative discography. Follow-up duration was one year at least with evaluations of VAS, recovery rate and satisfaction. Average age was 32 years.

The results were listed in table form and included back pain, VAS pre and post procedure, recovery rate, satisfaction, and complication. Group mean VAS pre procedure was 7.3 with post procedure being 4.9 for a group mean change of 2.4. However, eight patients (32%) complained of more pain after the treatment, three patients (12%) reported no treatment, and 14 patients (56%) reported less pain, with 44% of patients being dissatisfied with the procedure. Further, at least one year after the procedure, 21 of 25 patients complained of lingering back pain despite some relief of symptoms. It was not clear exactly when the follow-up times were recorded.

One patient developed discitis. At least one year after IDET, nearly half the patients were dissatisfied with their outcome and 20% (five including the discitis patient) underwent fusion. The authors concluded, "Although other studies have shown good results with IDET for at least 2 years, this investigation suggests the IDET may be somewhat less effective."

Spruit M, Jacobs WCH. Pain and Function after Intradiscal Electrothermal Treatment (IDET) for symptomatic lumbar disc degeneration. European Spine 2002;11:589-593.

The objective of this study was to evaluate the short-term effects of IDET for chronic discogenic low back pain. Twenty patients with symptomatic degenerative discs were treated with IDET and evaluated preoperatively, and three and six months postoperatively to evaluate whether the technique provided confidence for application in a larger population, "without exposing too many patients to unknown side effects or ineffective treatment." Outcome measures were the VAS, ODI, and the SF-36.

Demographics: mean (SD; range)

Age at operation (years)	37.6 (8.0; 26.1-56.2)
Duration of symptoms (months)	44.2 (32; 15-120)

Inclusion criteria:	**Exclusion criteria:**
Degenerative disc disease	Spondylolysis or spondylolisthesis
Affected level L1-S1	Infection
Predominant low back pain	Active malignancy
Intolerance for sitting	Pregnancy
Neurological exam normal	Previous lumbar surgery

Failed at least 6 month conservative care	
Informed consent	
Expected to complete follow-up	

Catheter protocol was a temperature increase to 90 degrees and then maintenance at 90 for four minutes (standard protocol). No antibiotics or steroids were used. Walking and exercise were encouraged. After six weeks patients were advised to resume normal activities. Ten patients had physiotherapy after three months.

Results:

	VAS			**ODI**		
	mean	**SD**	**range**	**Mean**	**SD**	**range**

	VAS			ODI		
Preoperative (n= 20)	65.40	14.89	42-96	42.10	7.35	26-52
3 months (n= 19)	56.31	25.34	10-95	39.00	16.15	6-68
6 months (n= 19)	50.63	26.52	2-100	36.68	21.07	0-64

The results showed that the VAS scores improved on average 14 points (100 point scale) (p= 0.046), however, the authors noted that the individual scores had great variation. The authors presented graphical display of individual scores over time which showed the variability. ODI did not improve significantly. The SF-36 improved on the vitality subscale (p= 0.023) and for bodily pain (p= 0.047). Sixteen patients were treated at one level and four were treated at two levels. One patient was lost to follow-up. No device-related complications (not defined) were reported.

The authors concluded, "Based on these results, we conclude that IDET is not effective in reducing pain and improving functional performance in a sample of 20 patients treated for chronic discogenic low back pain after 6 months follow-up."

Maurer P, Block J, Squilante D. Intradiscal electrothermal therapy (IDET) provides effective symptom relief in patients with discogenic low back pain. J Spinal Disord Tech 2008 21(1)55-62.
Maurer P, Squilante D. Is intradiscal electrothermal annuloplasty (IDET) effective treatment for discogenic low back pain? A prospective cohort outcome study identifying successful patient selection criteria. Proceedings of the NASS 16th Annual Meeting/ Spine J 2002; 37S.

The 2008 publication first appeared in abstract form in 2002. In the abstract, 78 patients were reported. In 2008, 56 patients were reported. These patients were enrolled between 1998 and 2002 at a single center trial of patients who participated in a sponsor-supported IDET registry. It was not clear how patients were recruited. The objective was stated as to evaluate back pain severity, physical function, and quality of life outcomes in highly selected patients with discogenic pain.

Inclusion criteria:

- Chronic low back pain and impaired function > 6 mo duration nonresponsive to conservative medical management
- < 50% disc height loss evidenced on plain AP and lateral xray
- Normal lower extremity neurologic examination
- At least 1 and < 3 desiccated discs with or without small, contained herniated nucleus pulposus evidenced by T2-weighted MRI
- Concordant pain provocation by low pressure (defined as < 50 psi)discography
- Posterior annular disruption

Exclusion criteria:

- Severe disc degeneration at one or more levels
- Extruded herniated nucleus pulposus
- Previous back surgery
- Chronic lower extremity radiculopathy
- Spinal canal stenosis > 30% by MRI or CT
- Spondylolisthesis

The study population was further defined by age (mean of 40 +/-11.6 years), duration of symptoms (mean 39 mo +/- 40mo) and number of patients receiving various treatments (unable to tell the average number of treatments that patients had), workmens compensation status and smoking. Other clinical characteristics were not listed. The procedure was described as a standardized heating protocol with little detail, such as if anything was injected into the disc. It did not say if they used anything for pain. No analgesics were mentioned. Physical therapy and rehab were initiated but the programs were not described and compliance was not given. Outcome measures were collected pretreatment and at three, six, 12, 18, and 24 months but visit protocol was not reported. Statistical methods compared baseline and final follow-up using matched pair t test, 2-tailed (it was not reported if the data met assumptions such as no skew). Some comparisons were done relative to the general US population though they did not give a reason as to why they used this population. Patients were followed for 12 to 24 months. Outcomes included VAS, sitting, standing, and walking tolerances, and SF-36 subscales. VAS was reported for only 50 patients with a pretreatment mean of 6.1 +/-1.8 and final follow-up mean of 2.4 +/-2.6. Forty-two patients were called a success by either a $\geq$ two point improvement in VAS, a 10 point improvement in SF-36 physical functioning or a 10 point improvement in SF-36 bodily pain. There were 14 patients that did not even meet one of the previous three criteria, and two went on to further spine surgery. Adverse events were listed by the author as, "No complications occurred during the IDET procedure and no postprocedural adverse events such as infections or neurologic sequelae were reported." Postprocedural was not defined. The authors concluded, "The findings of this study suggest that durable clinical improvements can be realized after IDET in highly selected patients with mild disc degeneration, confirmatory imaging evidence of annular disruption, and concordant pain provocation by low pressure discography."

Bryce D, Nelson J, Glurich I, Berg R. Intradiscal Electrothermal Annuloplasty Therapy: A Case Series Study Leading to new Considerations. Wisconsin Medical Journal. 2005.104(6):39-46.

The objective was to evaluate outcomes of IDET for chronic discogenic low back pain at a rural pain management clinic. Patients qualified to be in the study by meeting inclusion and exclusion criteria.

Inclusion:

- Chronic low discogenic back pain of at least 6 months
- No response to conventional treatment (no details given)
- Back pain represented > 60% of other symptoms (not defined)
- Normal score on neurological assessment tools including Zung Depression Scale and Modified Somatic Perception Questionnaire
- Lack of neurological neuropathy
- Positive provocative discography
- Posterior annular tears by CT classified as single discrete fissures or annular tears
- Age range from 18-50

Exclusion:

- Inflammatory arthritic
- Non-spinal instability
- Medical or metabolic disorders that would preclude patient follow-up or participation

Patients received IDET with the coil heated to 90 degrees for an average of 15 minutes. Patients wore a brace for six weeks post-op and had monitored physical therapy, but compliance was not reported. The Wilcoxon signed rank statistic was used to test the statistical significance of changes. Demographics and clinical characteristics that were reported are median age for males of 41 years (range 25-73) and 37 years for females (range 21-55) and number of males and females.

Eighty-six patients received IDET, 73 provided Roland Morris (RM) data at baseline. VAS and the RM Disability Questionnaire were collected at pretreatment, and post IDET at six weeks, three, six, 12, and 18 months (RM, current day VAS, and last week). VAS was reported for varying numbers of patients (23 for the 18 month outcome of VAS current day to 57 for 6 month RM). It was not reported why the patient numbers varied so much other than what the authors reported as, "Some patients were lost to follow-up at later time points."

Results at 6 months:

Measure	N	Mean	SD	Median	Minimum	Maximum	p
RM	57	-20.8	30.4	-12.5	-92	29	< 0.001
	38	-1.0	2.8	-0.2	-6.0	6.0	< 0.064

Measure	N	Mean	SD	Median	Minimum	Maximum	p
VAS (current day)							
VAS (last week)	39	-1.1	2.5	-1.0	-7.0	5.0	0.010

The authors concluded, "Data suggest that greater improvement in IDEA outcomes may be achieved by profiling the characteristics of patients who achieve the optimal long-term outcomes following treatment and should be considered during evaluation of patient eligibility for IDEA."

Singh V. Intradiscal Electrothermal Therapy: A Preliminary Report. Pain Physician 2000. 3(4):367-373.

The objective of this study was to investigate the effectiveness of IDET in patients with chronic functionally disabling discogenic low back pain. Patients who were enrolled had various previous treatments (number of treatments per patient not given).

Inclusion criteria:

- Back pain greater than 6 months
- Lack of response to conservative treatment
- Normal neurologic exam
- Absence of nerve-root tension signs
- Absence of compressive lesion on MRI
- Positive provocative discography
- Intensity of pain that limits function

Exclusions:

- Inflammatory arthritis
- Nonspinal conditions that could mimic lumbar pain (no details given)
- Medical disorders that would preclude appropriate follow-up

Twenty three patients were enrolled from a rural private practice in 1999. IDET was performed with the heating protocol "16.5 minutes in automode" and the final temperature being 80 to 90 degrees. Antibiotics were administered intradiscally (dose not given). Single and multiple levels were treated. Patients were followed at one, two, three, and six months post procedure and underwent rehabilitation. Paired tests were used for pre-and post procedure VAS scores and functional status. Two patients dropped out: one died and one moved away. Demographics and clinical characteristics reported were average age of 45 years (range 24 to 60) and an average duration of pain 92 months (range 6 to 384). Of the 21, three were receiving workers compensation. Seventeen of 21 patients were on narcotics. After IDET, narcotic use decreased by 29% (p= 0.063) (details of usage not given). Functional status was measured by tolerance (minutes) of sitting, standing, and walking, though it was not reported if this test was validated. It appeared that patients could sit, stand, and walk on average longer, but it is unknown if any of these results were clinically relevant and the p value was not a test of trend.

Results:

VAS	Pre IDET	Post IDET	Difference	P value
current	6.24 +/- 0.46	3.90 +/- 0.70	2.33 +/- 0.50	0.00
best	3.52 +/- 0.38	2.00 +/- 0.47	1.52 +/- 0.38	0.001
worst	8.38 +/- 0.37	5.71 +/- 0.74	2.67 +/- 0.57	0.00

Current, best and worst were not defined. The author also analyzed results based on patient perception of pain relief, where they found 67% of patients had at least 50% pain relief (other details of this measure were not provided such as validation, when it was recorded). The author concluded that IDET was a safe and effective procedure in patients with chronic, functionally limiting discogenic pain who did not respond to aggressive conservative modalities of treatments.

Derby R, Eek B, Chen Y, O'Neill C, Ryan D. Intradiscal Electrothermal Annuloplasty(IDET): A Novel Approach for Treating Chronic Discogenic Back Pain. Neuromodulation 2000;3(2):82-88.

The objective on the study was to investigate IDET in patients with chronic discogenic back pain. Thirty two patients were enrolled in 1997 (unclear how the patients were recruited). Inclusion criteria: back pain > 6 months, back pain > 60% of overall pain symptoms, lack of response to conservative treatment (undefined), normal neuro exam, negative straight leg raise, one or more positive discs on lumbar discography. Exclusion criteria were infections, bleeding diatheses, unstable medical conditions, and radiculopathy. In patients with more than two positive discs on discography, a clinical decision was made as to which levels to treat. Patients were judged to have either low pressure sensitive discs (pain < 15 psi) or high pressure (pain > 15 psi) sensitive discs. Patients' demographics and clinical characteristics reported were a mean age of 42 years, 17 females and 15 males, and 4 workers comp cases with seven patients having previous spinal surgery. Various heating protocols were used to various temperature of 75 to 150 degrees, eventually a standard protocol was developed with the final temperature being 80-90 degrees for 13.5 to 16.5 minutes (unclear how the this protocol was arrived at). The catheter position was assessed as fair, good or excellent. Six month and one year outcomes were assessed with an RM questionnaire, VAS scale, NASS low back pain satisfaction index and a general activity scale. At 12 month follow -up, the VAS had a mean decrease of 1.84 (SD 2.38) and the RM had a mean decrease of 4.03 (SD= 4.82). Overall activity level was better in 53.1% of patients, 34.4% said they were the same, and 12.5% were worse. All patients had a pain flare post procedure with a mean duration of five days. One patient underwent a fusion due to persistent pain. There were no infectious, neurologic, of bleeding complications. Interestingly, 61% with discrete annular fissures had a favorable outcome, with 64.3% of those with degenerative discs having a favorable outcome. Seventy-five percent of those with low pressure sensitive discs had a favorable outcome, while 55% with high pressure sensitive discs had a favorable outcome. The authors concluded that the study results suggested the IDET may be an effective, minimally invasive treatment for chronic discogenic low back pain.

Gerszten P, Welch W, McGrath P, Willis S. A Prospective Outcomes Study of Patients Undergoing Intradiscal Electrothermy (IDET) for Chronic Low Back Pain. Pain Physician 2002; 5(4):360-364.
Welch W, Gerszten P, McGrath P. Intradiscal Electrothermy Indications, Techniques, and Clinical Results. Clinical Neurosurgery 2001;48:219-225.

Gerszten reported on 27 patients with low back pain enrolled January 2000-October 2001. Welch appeared to report on the three month outcomes for 23 patients from this group. Gerszten stated patients were evaluated in a neurosurgery spine clinic while Welch describes it as an outpatient setting. It was not clear how the patients were recruited.

Inclusion:

- Persistent low back pain of at least 6 months
- Low back pain greater than leg pain
- Discogenic pain defined as pain with tasks requiring axial loading of the spine and relief of pain with recumbency
- MRI scan with disc desiccation, high intensity zone in the disc, disc rupture, loss of disc height, or concordant provocative discography
- Failure on conservative care in the prior 6 months

Exclusion:

- Instability(> 5mm of subluxation)
- Active infections
- Malignancy
- Metabolic disorder that would preclude appropriate follow-up and participation

In Gerszten, eight had only MRI, refusing discography. Nine patients had only low back pain. Several patients were offered IDET as they were felt to be too high a risk for fusion. Catheter temperature was increased to 90 degrees over 13 minutes and held at that temperature for four minutes. Antibiotics were not injected into the disc. Patients were instructed to resume their activities as tolerated after 24 hours. SF-36 scores and ODI were collected at baseline, six weeks, three months, and one year after treatment. Patients' demographics included 15 men and 12 women, mean age 41 years. Mean duration of symptoms was 38 months (range six months to 15 years). Patients were treated at one and two or more disc levels.

Results:

Scales	Baseline mean score	Post-treatment mean score
SF-36 physical functioning subscale	32	47
SF-36 bodily pain subscale	27	38
	5	16

Scales	Baseline mean score	Post-treatment mean score
SF-36 role functioning physical		
ODI	34	30
Neurogenic symptoms	15	14

The above results were for one year outcomes. Patient numbers were unclear. In Gerszten, there were no nerve root injuries or infections and cerebral spinal fluid was visualized in one case. In one case, the catheter could not be threaded secondary to scare tissue and this patient underwent a fusion. However, in Welch, two patients had dural punctures and five patients went on to further surgery. In the one year follow-up of Gerszten, they concluded that the procedure may be useful in patients who would otherwise undergo an interbody fusion.

Davis T, Delamarter R, Sra P, Goldstein T. The IDET Procedure for Chronic Discogenic Low Back Pain. Spine 2004;29(7):752-756.

This study was a retrospective review of 44 patients of 60 who responded to a telephone interview and completed a self-administered questionnaire approximately one year post-IDET. The objective was to assess functional status, symptoms and subsequent treatments of patients treated with IDET. Patients were recruited from 17 spine specialists that referred patients to one ambulatory surgery center for IDET from May 1999 to December 2000. Average patients' age was 40 years (range 25-64) with 66% makes and 34% females. All patients had a positive discogram, a diagnosis of discogenic low back pain, and had failed other conservative management. With discography, it was considered positive if the patients experienced concordant pain of pressurization with < 2.5 mL of contrast and there was a painless pressurization of a control level.

Inclusion:

- Internally disrupted disc with an annular fissure
- Contained disc herniation
- Positive discogram
- Symptoms > 6 months
- Disc height > 50%
- Failed conservative care

Exclusion:

- Stenosis
- Frank disc herniation or sequestered discogenic evidence of neural compression on MRI
- Previous lumbar surgery
- Overlying psychological issues
- Segmental instability

A trained, independent interviewer conducted the phone interview. Questionnaires were comprised of question from the National Low Back Pain Study forms A and D. Of 44 patients, six patients had lumbar surgery within a year (these patients were not included in the analysis).

Results for 38 patients:
Pain:

- 97% (37) continued to have back pain
- 29% (11) had more pain post IDET
- 39% (15) had less pain
- 29% (11) reported no change in pain

Pain medication:

- 29% (11) reported using more pain medication post-IDET
- 26% (10) used the same
- 32% (12) used less
- 13% (5) used none

Patient satisfaction:

- 50% (19) were dissatisfied with IDET

- 37% (14) were satisfied
- 13% (5) were undecided

Employment:

- 42% (16) were employed full-time pre-IDET
- 29% (11) were employed full-time post-IDET

Most patients wore a brace > 6 hours/day after surgery (duration 1-15 months). The authors concluded, "At 1-year post-IDET, half of patients were dissatisfied with their outcomes."

Webster B, Verma S, Pransky G. Outcomes of Workers' Compensation Claimants with Low Back Pain Undergoing Intradiscal Electrothermal Therapy." Spine 2004:29(4):435-441.

The objective of this study was to describe the outcomes of workers compensation claimants who had IDET. Low back pain cases that underwent IDET between December 1, 1998 and February 29, 2000 were identified from records. Outcomes included narcotic use six months or more after IDET, additional invasive treatment after IDET, and improved work status 24 months after IDET. One hundred forty-two cases from 23 states were identified, with 97 different providers performing the procedure. Mean duration of symptoms before IDET was 26 months. Mean follow-up duration after IDET was 22 months.

Results:

- Ninety-six (68%) of the cases did not meet one or more of the published inclusion criteria.
- Seventy-eight cases (55%) received at least two narcotic prescriptions 6 months or more after IDET.
- Fifty-three (37%) had at least one lumbar injections 32 (23%) had lumbar surgery after IDET.
- Fifty-five (39%) were working at 24 months after IDET.

The authors found that the need for invasive lumbar procedures after IDET were associated with provider self-referral (the same provider performing discography and IDET), narcotic use before IDET and older age. The authors concluded that, "Randomized controlled trials are needed to determine whether there is a subset of patients with discogenic back pain who derive substantial and sustained benefit from this procedure."

Endres S, Fiedler G, Larson K. Effectiveness of Intradiscal Electrothermal Therapy in Increasing Function and Reducing Chronic Low Back Pain in Selected Patients. Wisconsin Medical Journal.2002;101(1):31-4.

The purpose of this study was to analyze the effectiveness of IDET in reducing chronic low back pain and increasing function in selected patients in the authors' practice. Patients who underwent IDET in the authors' pain management practice from April 1998 until "the present" were reviewed.

Inclusion criteria: low back pain > 9 months; unresponsive to conservative measures (number of treatments per patient not given); MRI with degenerative changes such as disc desiccation, annular tears, or HIZ lesions; positive discography (pressure/volume not given); post-discography CT demonstrating annular disruption to the outer third of the annulus. Exclusion criteria included: disc height < 50%; previous back surgery; known spinal stenosis; significant disc protrusion with obvious neurocompressive lesion with associated radicular symptoms; MRI with neurocompressive lesion. Patients wore a corset for one month post-IDET and were followed by a physical therapist. Telephone follow-up was done by a nonbiased observer to assess VAS, sitting and walking tolerances, work status and it they would do the procedure again. The group had 54 patients with a mean age of 40 years (range 17-63). Follow-up time varied between 12 weeks and 108 weeks. Thirty-four patients had the procedure at one level, and 20 at two. Seventeen patients had a change of VAS less than two while 30 patients had a change of two or more, but it does not appear that the follow-up time was uniform for all patients (12 weeks to 108 weeks). Mean sitting and walking scores were for 52 to 54 patients and improved on average 20 to 30 minutes though the significance of this was not mentioned. It was not mentioned why fewer patients had VAS scores than sitting and walking tolerances. No complications were noted in any of the patients under review (complications were not defined). Thirty-five patients (66%) returned to work and thirty-seven patients (76%) said they would do the procedure again. The authors concluded that IDET appeared to be a safe, efficacious and inexpensive treatment for back pain related to internal disc disruption.

Cohen S., Larkin T, Abdi S, Chang A, Stojanovic M. Risk Factors for Failure and Complications of Intradiscal Electrothermal Therapy: A Pilot Study. Spine 2003;28:1142-1147.

The purpose of the bi-institutional study was to identity risk factors for failed IDET and to describe complications with this procedure based on patients self-report. Charts of 80 patients who underwent 109 IDETs between 1999 and 2002 were reviewed. One patient could not have the catheter threaded to the proper position and was excluded. To be considered as having discogenic pain a patients had to have one or more discs with a grossly abnormal radiologic MRI and positive discography meaning at least 6/10 concordant pain at less than 50 psi above opening pressure when contrast was injected into the disc. Patients also had to have at least one adjacent control disc. Inclusion criteria were: back pain > 6 months; lack of response to conservative treatment; absence of prominent radicular signs and symptoms; and positive provocative discography. Exclusion criteria included: age > 60; severe spinal stenosis; loss of more than 50% disc height; significant spondylolisthesis, inflammatory arthritis; unstable medical conditions that would preclude participation and follow-up such as cardiac patients taking anticoagulants. The catheter protocol was to heat to a temperature of 90 degrees over 16.5 minutes. Ten patients could not tolerate the full heating period so in these patients it was terminated early. Cefazolin antibiotic (dose not mentioned) and 0.5% bupivacaine were administered intradiscally. After the procedure the patients had a lumbar support brace. Patients began a lumbar stabilization program in the second post-op month. The primary outcome measure was pain relief with the VAS collected at two, four, and six months. Variables analyzed for their association with complications and failure were: age, sex, duration of pain, presence of nonradicular leg pain, smoking, diabetes, obesity, previous back surgery, and number of levels. Categorical data was analyzed by Chi squared tests, and continuous data by t tests. The average age of the 79 patients was 38 years (range 15-60), with the mean duration of low back pain 5.7 years (range 1-22). Of the 79 patients, there were 15 smokers (19%), three with diabetes (4%), and 10 patients who were obese. Thirty eight patients were judged to have a positive outcome with the pre-IDET VAS mean for this group of 5.9 (SD1.8) and the post VAS mean of 2.1 (SD1.3), while 41 patients had a negative outcome with a pre-IDET VAS of 6.2 (SD1.9) and a post-IDET VAS of 5.1 (SD 1.8). There was a 10% (8 patients) complication rate, which were described in the study and were mostly self-limited. The authors concluded, “The only risk factor found to be associated with IDET outcome was obesity, which was a strong predictor of failure.”

Derby R, Lee SH, Seo KS, Kazala K, Kim BJ, Kim MJ. Efficacy of IDET for Relief of Leg Pain Associated with Discogenic Low Back Pain. Pain Practice 2004. 4(4):281-285.

This study was performed to assess the long-term efficacy of IDET for the treatment of referred leg pain in chronic discogenic LBP. Data from January 1999 to December 2000 were retrospectively analyzed. Among 129 patients who underwent IDET, 30 patients underwent subsequent back surgery and were excluded from the study giving a total of 99 patients. Inclusion criteria included: back pain with referred leg and buttock pain of > six months; lack of response to conservative measures; absence of tension signs during straight-leg raising, non-focal neurological abnormalities, MRI negative for nerve root compression; disc protrusion $\leq$ 2mm and positive discogram with annular tear. Exclusion criteria included: allergy to contrast or cephalosporins; inability to tolerate MRI; patients with unstable medical conditions; previous spinal surgery; instability; spondylolisthesis; spinal stenosis; disc height < 50%; inability to speak English. IDET total treatment time was 13.5 to 16.5 minutes, achieving a final temperature of 80-90 degrees. The standard protocol was terminated at back pain > 6/10, but if tolerated by the patient, the final temperature was maintained for an additional 4 minutes. After treatment their physical activities were restricted for the first six weeks. Patients were encouraged to walk and do exercises. The VAS for total body pain, five point scales for back and leg pain were collected (not clear at what visits the data was collected or if this scale has been validated). The Mann-Whitney U-test was used for statistical analysis, with the chi-squared test for non-parametric parameters. Mean patient age was 42.7 years (range 17-62 years) and 83 patients had leg pain without sciatica. The average follow-up time was 18 +/- 4 months. The VAS score change showed 1.13 +/-3.13, (LBP > leg pain), 2.28 +/- 2.49(LBP = leg pain), 2.64 +/- 3.41 (LBP < leg pain). The mean improvement in the five-point pain score was 1.90/4. The authors concluded, "These data suggest that IDET may relieve associated limb pain in chronic discogenic LBP patients."

Freedman B, Cohen S, Kuklo T, Lehman R, Larkin P, Giuliani J. Intradiscal Electrothermal Therapy (IDET) for Chronic Low Back Pain in Active-Duty Soldiers: 2-year follow-up. The Spine Journal 2003;3:502-509.

The purpose of this study was to report the outcomes with IDET in the management of chronic discogenic low back pain in Active-Duty Soldiers. The primary outcome was pain relief. Data from 41 active-duty soldiers between 1999-2001 was collected. Only the results of 36 patients were analyzed as five underwent two trials of IDET. The success rate (defined as a stated, "50% decrease in pain from baseline) was 47% (17 of 36) at six month follow-up and 16% (5 of 31 patients) at latest follow-up. Though stated success rates were low, the authors commented that 20 of 31 soldiers had a persistent decrease in their pain score (average decrease of 2.5 +/- on a 10 point scale), with 52% having 2-point or greater decrease. The complication rate was 16% (5 of 31: foot drop; increased disc herniation; fecal incontinence; increased or new nondermatomal leg pain times two). Seven of 31 soldiers (23%) went on to spinal surgery within 24 months of failed IDET. The authors concluded, "IDET is not a substitute for spinal fusion in the treatment of chronic discogenic low back pain in active-duty soldiers."

Derby R, Eek B, Lee SH, Seo KW, Kim BJ. Comparison of Intradiscal Restorative Injections and Intradiscal Electrothermal Treatment (IDET) in the Treatment of Low Back Pain. Pain Physician 2004;7:63-66.

The purpose of this study was to examine the effectiveness of injections and compared these results with the effectiveness of IDET. This study was performed, per the authors, retrospectively through the analysis of a prospectively collected database. The patients were referred from primary care and other clinicians during January 2000 to October 2002. There were 74 patients mean age 42 years (range 17-62 years) that received IDET. All patients had positive discography with annular tear, had failed to respond to conservative care, had non-focal neurologic exam, disc protrusion $\leq$ 2 mm, and single level pathology. Patients with allergy to contrast media or cephalosporin antibiotics, unstable medical conditions, instability and spondylolisthesis, severe spinal stenosis, and reduced disc height > 50% were excluded. Outcomes were assessed with the VAS and with a subjective evaluation sheet. Patients were followed from 6-18 months. Thirty five patients with an average age of 42 years received injections. The authors stated there were no significant differences in the essential demographic characteristics of the groups. The authors stated the outcome as, "Pain relief was statistically significant for both procedures, but slightly better for injections (2.2 VAS) than for IDET (1.27 VAS), although the difference was only marginally significant (p= 0.01)." They also noted that 35.8% of IDET patients reported that they were worse, while no restorative injection patient reported worsening of pain. The authors concluded, "Clinical efficacy is similar to that of IDET, but with an improved cost -benefit ratio."

Ergun R, Sekerci Z, Bulut H, Dolgun H. Intradiscal electrothermal Treatment for Chronic Discogenic Low Back Pain: a Prospective Outcome Study of 39 Patients with the Oswestry Disability Index at 18 Month Follow-Up. Neurological Research 2008;30:411-416.

The authors stated that this study done in Turkey was to evaluate the efficacy of IDET for discogenic pain using the ODI after 18 month follow-up. Thirty nine patients were enrolled that had one or two-level disease. Patients who received two level treatment received the second treatment one week after the first. Demographics and clinical characteristics listed were mean age was 41 years (range 20-62) with mean duration of back pain 32 months (range 14-72). Discography was considered positive if the patient experienced concordant pain with 2.5 mL contrast agent. Standard protocol to 90 degrees was used. No antibiotics or corticosteroids were used. The Turkish ODI was used before treatment and at six,12 and 18 months. For comparison of median scores, the Friedman test was used, and for comparison of mean ranks and level of statistical significance, Bonferroni-Dun correction was used. A brace was given post-op. Gradual exercise was encouraged with normal activities after six weeks. There were no device-related complications, though the authors also stated that one patient converted to a large herniation and then underwent surgical decompression. There were no details provided on concomitant treatment such as analgesics, steroid injections, or physical therapy so the effect size is difficult to attribute solely to the IDET treatment. The window for follow-up visits was not given.

Results for 39 patients (unclear if the patient with complication is included)

ODI	mean	SD	Min	Max	Effect Size (Cohen)
baseline	46	12	24	72	

ODI	mean	SD	Min	Max	Effect Size (Cohen)
6 months	25	11	2	48	1.67
12 months	23	11	2	46	1.81
18 months	22	10	4	46	1.92

The authors concluded, "The current study of 39 patients with chronic unremitting low back pain of discogenic origin whose symptoms had not improve[sic] with aggressive non-operative care demonstrated a statistically significant and clinically meaningful improvement on the ODI scores at a minimum follow-up of 18 months after IDET."

Biacuplasty

Kapural L, Ng A, Dalton J, Mascha E, Kapural M, Garza M, Mekhail N. Intervertebral disc Biaculoplasty for the Treatment of Lumbar Discogenic Pain: Results of a Six-Month Follow-up. Pain Medicine 2008:9(1):60-67.

This study is a pilot trial with 6-month follow-up of fifteen (only thirteen completed the trial) patients that underwent one or two level biacuplasty (IDB) treatment for chronic low back pain after they were denied IDET by their insurance company.

Inclusion criteria:

- chronic low back pain unresponsive to conservative care > 6 months
- back pain > leg pain that is commonly exacerbated by sitting
- concordant pain on provocative discography
- disc height $\geq$ 50% of adjacent control disc
- one or two level degenerative disease without evidence of additional changes (undefined) on MRI

Exclusion criteria:

- evidence of compressive radiculopathy
- nucleus pulposus herniation on MRI
- disc bulges exceeding 5mm
- prior surgery at the symptomatic level
- symptoms or signs of lumbar canal stenosis
- pending workers Compensation claim
- psychological issues
- tumor
- systemic infection
- traumatic spinal fracture
- history of coagulopathy
- unexplained bleeding
- progressive neurological deficits
- current use of long-acting opioids or history of opioid abuse
- presence of free disc fragments on MRI
- manual labor
- smoking
- BMI > 30
- Age > 55

Demographics and clinical characteristics were age range from 22 to 55 years and Beck Depression Inventory ranges from 1 to 13. One patient withdrew and another was removed due to litigation related to her back pain. Patients were given IV midazolam, fentanyl and antibiotics before the procedure. The probe temperature was increased to 55 degree over 11 minutes, then maintained for an additional 4 minutes. Post op patients were given a brace and given a physical therapy regimen. Baseline VAS, ODI, opioid use and SF-36 were collected at baseline and then one, three and 6 months post procedure. It was stated that the ODI, SF-36 physical function and bodily pain were normally distributed at each time point, a repeated measures analysis of variance was used. For non-normally distributed endpoints (VAS and opioid use), the Wilcoxon signed rank test of location difference between time points and Friedman's chi-square test for ranks for the overall test were used. A Bonferroni adjustment was used for multiple comparisons.

Estimated changes in outcomes across time (Estimated difference with 95% confidence interval)
N= 13 patients

variable	Baseline-1 months	Baseline-3 months	Baseline-6 months
ODI*	6.8(3.1,10.6)	6.4(2.7,10.1)	6.2(2.5,10.0)
SF-36 physical function*	-8.6(-17.4,0.1)	-14.9(-23.5,-6.3)	-19.2(-29.7,-8.6)
SF-36 bodily pain*	-12.2(-22.3,-2.0)	-13.7(-23.8,-3.6)	-16.2(-26.4,-6.1)
VAS#	3(2,7)	3(2,3)	3(2,6)
Opioid use#	0(0,40)	20(0,40)	20(0,70)

*estimated pair-wise differences in means based on a repeated measures mixed model
#estimated median differences based on pair-wise Wilcoxon signed rank tests

No patients had worse pain scores six months after the procedure. One patient was considering spine fusion surgery. No procedure-related complications (undefined) were detected. The authors concluded, "A randomized controlled study is warranted and needed to address the efficacy of the procedure."

Percutaneous Disc Decompression

Sharps L, Isaac Z. Percutaneous Disc Decompression using Nucleoplasty. Pain Physician 2002;5(2):121-126.

The objective of this study was to evaluate the effectiveness of nucleoplasty for decompression of contained herniated discs in a single site study of 49 patients.

Inclusion criteria:

- back pain with or without radicular pain
- failure six weeks of conservative care (posture and activity modifications, physical therapy, NSAIDs, including steroid injections without radicular symptoms)

Exclusion criteria:

- presence of a sequestered herniation
- a contained herniation > 1/3 the sagittal diameter of the spinal canal
- spinal stenosis
- presence of progressive neurological deficits
- tumor
- infection
- spinal fracture

The treating physician and support staff obtained the follow-up assessments. Success was defined as a minimum reduction in VAS of two points, patient's satisfaction, absence of narcotic use, and return to work if not working secondary to back pain. At three weeks post procedure formal physical therapy was started.

Results:

VAS	
baseline (49)	7.9 $\pm$ 1.3 (3-10)
one month (49)	3.6 $\pm$ 2.6 (0-9)
three month (41)	3.1 $\pm$ 2.7 (0-9)
sex month (24)	3.2 $\pm$ 2.8 (0-9)
twelve month (13)	4.3 $\pm$ 2.8 (0-9)

The mean post-procedural satisfaction measured on a four point score was 2.14, good. No post-procedural complications were observed. Narcotic use and return to work were not mentioned. The authors concluded that, "Results indicate that Nucleoplasty may be a promising and efficacious minimally invasive procedure for the treatment of symptoms associated with contained herniated discs."

Singh V, Piryani C, Liao K, Nieschulz. Percutaneous Disc Decompression Using Coblation (Nucleoplasty) in the Treatment of Chronic Discogenic Pain. Pain Physician 2002;5(3):250-259
Singh V, Piryani C, Liao K. Evaluation of Percutaneous Disc Decompression Using Coblation in Chronic Back Pain with or without Leg Pain. Pain Physician 2003; 6:273-280.
Singh V, Piryani C, Liao K. Role of Percutaneous Disc Decompression using Coblation in Managing Chronic Discogenic Low Back Pain: a Prospective, observational Study. Pain Physician 2004;7:419-425.

These three case series with the objective to evaluate safety and efficacy of PDD in discogenic back pain by Singh are similar.

Inclusion criteria by year:

Contained disc herniation	2002	2003	
Back pain and/or leg pain > 3 months	2002	2003	

Absence of neurologic deficit	2002	2003	2004
Lack of response to conservative care and injection	2002	2003	2004
Positive provocative discography	2002	2003	2004
Pain of 5 or greater			2004

Exclusion criteria:

Litigation	2002		2004
Heavy opioids usage	2002	2003	2004

Uncontrolled psychological disorders	2002	2003	2004
Disc herniation with sequestration	2002	2003	2004
Large contained herniation	2002	2003	2004
Evidence of infection	2002	2003	2004
Spinal instability	2002		2004
Marked spinal stenosis	2002	2003	2004
Presence of secondary gain issues (undefined)		2003	

The coblation procedure description was similar in all three reports. Post-operative care included a gradual increase in activities. There was no report of formal physical therapy or description of an exercise program other than "home exercise instructions." Outcome measures included a numeric pain score (0-10), improvement in ability to sit, stand, and walk by time (measured in minutes). Follow-up values were collected at one month, three months, six months, and 12 months. It was not disclosed if there was overlap in the patient populations from year to year. The authors stated that for outcomes and nonparametric values, 95% confidence intervals and paired t-tests were used.

Demographics and clinical characteristics

	2002	**2003**	**2004**
Age, mean (range)	44 (15-62)	44.8 (15-62)	44 (15-62)
Gender, male(M), female (F)	20 M (30%) 47 F (70%)	24 M(30%) 56 F (70%)	15 M (32%) 32 F(68%
Duration of pain, mean (range)	5.4 years (0.5 – 29 years)	5.5 years (0.25-30 years)	6.3 years (0.5-29 years)
Smoking, %	40%	35%	32%

Results:

	2002	2003	2004
Patients at baseline	67	80	47
Patients included in 6 month follow-up	61	72	40
Patients included in 12 month follow-up	41	69	37
Numeric pain score, average $\pm$ SD, baseline	6.8 $\pm$ 1.1	6.8	6.7 $\pm$ 1.1
Numeric pain score, average $\pm$ SD, 6 months	4.2 $\pm$ 2.6	4.2	3.9 $\pm$ 2.7
Numeric pain score, average $\pm$ SD, 12 months	4.1 $\pm$ 2.5	4.5	4.4 $\pm$ 2.3

	2002	2003	2004

The authors reported that sitting, standing, and walking improved by percentage of patients reporting improvement (unclear if this was validated).

The 2002 and 2004 reports stated there were no complications during the procedure or post-operatively, specifically discitis or neurological deficit related to the procedure. The 2003 report stated that there were no complications during the procedure or post-operatively, specifically no discitis, dural tear, or neurological deficit related to the procedure. The authors conclude in each article that PDD using Coblation technology (also referred to as Nucleoplasty) was an effective procedure.

Yakovlev A, Tamimi M, Liang H, Eristavi M. Outcomes of Percutaneous Disc Decompression Utilizing Nucleoplasty for the Treatment of Chronic Discogenic Pain. Pain Physician 2007;10:319-327.

The objective of this study was to evaluate the effect of nucleoplasty on pain and opioid use in improving functional activity in patients with radicular or axial low back pain secondary to contained herniated discs. The study was retrospective with patients having PDD between February 2004 and August 2005. Twenty-two patients were evaluated at one, three, six and 12 months postoperatively with the VAS and were surveyed as to pain medication use. Functional status was quantified by a physical therapist. Mean age was 39 (range 22 – 51 years).

Inclusion:

- Duration of radicular or axial low back pain or six or more months with failed conservative treatment (including injections)
- No history of neurological deficit
- < 50% disc height loss
- Positive concordant discography contained disc protrusion on MRI

Exclusion:

- Infection
- Spinal tumor
- More than two symptomatic levels
- Disc sequestration or spinal stenosis on MRI
- History of open disc surgery at suspected level
- Prominent coexisting psychological disorders

The Wilcoxon matched-pairs signed-ranks test was used for VAS pain score analysis.

The baseline VAS mean was 7.6 (SD 1.2), six months VAS mean 4.2 (SD 3.1), and 12 months VAS mean 3.6 (SD 3.2). The authors reported the result as difference from baseline without an error estimate: six months -3.63, signed-ranks test p value of < 0.0001; 12 months -3.98, signed-ranks test p value of < 0.0001. The authors reported physical function significantly improved (as noted by the physical therapist) and at 12 months 63% of patients retuned to work. Sixty-four percent reported a reduction in opioids (unclear what is considered a reduction) intake at six months and 73% at one year. Concomitant treatments such as injections were not mentioned.

The authors reported no complications associated with the procedure. The authors concluded, "Nucleoplasty appears to be safe and effective. Randomized, controlled studies are required to further evaluate its long-term efficacy."

Masala S, Massari F, Fabiano S, Ursone A, Fiori R, Pastore F, Simonetti G. Nucleoplasty in the Treatment of Lumbar Diskogenic Back Pain: One Year Follow-up. Cardiovascular and Interventional Radiology 2007;30:426-432.

This study was done to evaluate the efficacy of nucleoplasty coblation for discogenic pain. Seventy-two patients (mean age 48 years) were included in this Italian study.

Inclusion criteria:

- Presence of lumbalgic and/or sciatolgic pain due to diskal protrusions and contained herniations
- Absence of major neurologic deficit
- Lack of response after six weeks of conservative management
- Positive provocative discography

Exclusion criteria:

- Presence of secondary gain issues
- Litigation
- Heavy opioid usage
- Uncontrolled psychological disorders
- Sequestered or extruded disk herniation
- Contained herniation that was larger than 1/3 of the sagittal diameter of the spinal canal
- Severe degenerative disc (defined as > 33% loss of disc height)
- Spinal stenosis
- Previous spinal surgery in the same region
- Spondylolisthesis
- Bone congenital abnormalities
- Evidence of infection
- Cauda equina syndrome
- Tumor
- Spinal instability

Two patients were lost to follow-up. Student's t-test was used for statistical analysis. The average preprocedural pain level was 8.2, while the average pain level at 12 months of follow-up was 4.1. Seventeen percent of patients were completely satisfied with complete resolution of symptoms and 79% of patients demonstrated a statistically significant improvement in VAS. The authors commented in the results section that at one-year follow-up MRI examinations were done which reported a reduction in lesions in almost 80% of patients, but they didn't clearly discuss what lesion they were referring to. An assumption could be that they were referring to small and contained disc herniations, for which the natural history is shrinkage within 8-9 months. The authors concluded, "Our data indicate that nucleoplasty coblation is a promising treatment option for patients with symptomatic disk protrusion and herniation who present with lumbalgic and/or sciatalgic pain, have failed conservative therapies, and are not considered candidates for open surgery."

Mirzai H, Tekin I, Yaman O, Bursali. The results of nucleoplasty in patients with lumbar herniated disc: a prospective clinical study of 52 consecutive patients. The Spine Journal 2007;7:88-93.

The authors stated that the purpose of this study was to evaluate the efficacy of nucleoplasty technique in patients with leg pain caused by radicular encroachment. Fifty-two patients were enrolled with a mean age of 45 years.

Inclusion criteria:

- Radicular pain resistant to previous medical treatment and physical therapy > 3 months
- Signs of root-ganglion irritation
- Contained disc herniation < 6 mm
- Disc height $\geq$ 50% in comparison to normal adjacent disc

Exclusion:

- 60 years of age
- Significant spinal stenosis
- Fracture

- Tumor
- Spondylolisthesis
- 6mm or extruded disc herniation on MRI
- Back pain greater than leg pain
- Complete annular disruption on MRI or discography

The procedure was done by a single surgeon. Thirty-four patients had one disc and 18 had two discs treated. Three patients were lost to follow-up. The mean follow-up was 12 months. The VAS and ODI were collected at two weeks and six months by the surgeon and one year by an independent examiner. Reduction of analgesic treatment and patient satisfaction were also recorded. The authors reported no complications related to the procedures.

Clinical Outcomes (mean $\pm$ SD)

Outcome	**baseline**	**6 months postprocedure**	**At least 12 months postprocedure**
VAS	7.5 $\pm$ 1.3 (6-10)	3.1 $\pm$ 2.3 (0-9)	2.1 $\pm$ 1.6 (0-6)
ODI	42.2 $\pm$ 5.5 (36-60)	24.8 $\pm$ 11.3 (12-60)	20.5 $\pm$ 8.9 (10-50)
Number of patients requiring analgesics	52 (100%)	Stopped or reduced 42 (85%)	Stopped or reduced 46 (94%)
Patients satisfaction		Satisfied or very satisfied 85%	Satisfied or very satisfied 88%

Outcome	baseline	6 months postprocedure	At least 12 months postprocedure

The authors concluded, "We recommend applying this minimally invasive technique only in those patients with small (< 6mm) contained disc herniations, with a disc height of $\geq$ 50% and with annular integrity."

Cohen S, Williams S, Kurihara, Griffith S, Larkin T. Nucleoplasty with or without Intradiscal Electrothermal Therapy (IDET) as a Treatment for Lumbar Herniated Disc. J Spinal Disord Tech 2005;18:S119-S124.

The authors stated, "Among the therapeutic options to emerge are a plethora of minimally invasive treatments aimed at removing nuclear material and lowering intradiscal pressure though devices inserted percutaneously into intervertebral discs. Yet there is a compelling lack of clinical evidence to support the use of these procedures. This study was undertaken to determine the treatment outcomes of 16 consecutive patients with lumbar radicular pain secondary to a herniated disc who underwent nucleoplasty as their primary therapy." Nine patients with significant axial back pain, sitting intolerance, and positive discography also underwent IDET. Mean age was 37 years old. The mean duration of pain was 5.3 years (range 1-20 years).

Inclusion criteria:

- Lower leg pain with or without back pain of > 6 months
- Poor response to conservative treatment including injections
- MRI evidence of small herniated or protruding disc
- Radicular symptoms with leg pain greater than back pain

- Disc height of ≥ 50%

Exclusion criteria

- Age > 60 years
- Significant spinal stenosis
- Significant spondylolisthesis
- MRI with a large, uncontained disc herniation
- Back pain greater than leg pain
- Unstable medical condition

In the total cohort, the average VAS decreased from 6.7 to 5.6 at a mean follow-up of nine months. In the seven patients who underwent only nucleoplasty the mean VAS score decreased from 6.0 to 4.8. Only one patient reported a > 50% reduction in pain score. The authors concluded, "It is our opinion that nucleoplasty is not the correct procedure for patients with discogenic, axial low back pain, even with IDET. More research is needed to determine which patients, if any, are the best candidates for nucleoplasty."

Appendix C
CMS Evidence Table for Thermal Intradiscal Procedures
[PDF, 69KB]

Appendix D
References cited in public comments on proposed decision memorandum

Anderson GB, Mekhail NA, Block JE. Treatment of intractable discogenic low back pain. A systematic review of spinal fusion and intradiscal electrothermal therapy (IDET). Pain Physician 2006; 9:237-248.

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Appendix E

DRAFT
Medicare National Coverage Determinations Manual Chapter 1, Part 2 (Sections 90 – 160.25) Coverage Determinations

Table of Contents

(Rev.)

150.20 – Thermal Intradiscal Procedures (TIPs) (Effective XX XX, 2008)

(Rev. ,)

A. General

Percutaneous thermal intradiscal procedures involve the insertion a catheter/probe(s) in the spinal disc under fluoroscopic guidance for the purpose of producing or applying heat and/or disruption within the disc to relieve low back pain.

The scope of this national coverage policy on TIPs includes percutaneous intradiscal techniques that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for coagulation and/or decompression of disc material to treat symptomatic patients with annular disruption of a contained herniated disc, to seal annular tears or fissures, or destroy nociceptors for the purpose of relieving pain. This includes techniques that use single or multiple probes/catheters, which utilize a resistance coil or other delivery system technology, are flexible or rigid, and are placed within the nucleus, the nuclear-annular junction or the annulus.

Although not intended to be an all inclusive list, TIPs are commonly identified as intradiscal electrothermal therapy (IDET), intradiscal thermal annuloplasty (IDTA), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), radiofrequency annuloplasty (RA), intradiscal biacuplasty (IDB), percutaneous (or plasma) disc decompression (PDD) or coblation, or targeted disc decompression (TDD). At times, TIPs are identified or labeled based on the name of the catheter/probe(s) that is used (e.g., SpineCath, discTRODE, SpineWand, Accutherm, or TransDiscal electrodes). Each technique or device has it own protocol for application of the therapy. Percutaneous disc decompression or nucleoplasty procedures that do not utilize a radiofrequency energy source or electrothermal energy (such as the disc decompressor procedure or laser procedure) are not within the scope of this NCD.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

Effective for services performed on or after XX XX, 2008, CMS has determined that TIPs are not reasonable and necessary for the treatment of low back pain. TIPs which include procedures that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain are ***noncovered****.*

D. Other

N/A

(This NCD last reviewed XX 2008)

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[1] Nociceptors are free nerve endings, found throughout the body including the annulus fibrosus portion of the intervertebral disc, which act as sense organs that send signals that cause the perception of pain in response to potentially damaging stimulus.

[2] Ramus communicans is any of the bundles of nerve fibers connecting a sympathetic ganglion with a spinal nerve.

Back to Top

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Back to Top